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Agenda Item 5 **CX/MAS 20/41/7 Add.1**

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

REVISION OF THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CXG 54 – 2004)

Comments at in reply to CL 2020/31-MAS

Comments of Canada, Chile, Egypt, Honduras, Iraq, Japan, New Zealand, Norway, Peru, Thailand, Uruguay, USP

NOTE: CCMAS41 has been postponed to 17 – 21 May 2021. In order to ensure work continuity, CL 2020/31/OCS was issued requesting further comments. See background information in the aforementioned CL. The comments compiled in this document will be made available to Germany for further consideration and preparation of a revised version of the Guidelines for consideration by CCMAS41.

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2020/31-MAS issued in May 2020. 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 COMMENTS
Uruguay Uruguay thanks Germany for the work done that shows a significant improvement in the document compared to its latest version. Some little editorial and structural changes are still required.
Chile 1. In relation to the Draft revision of the Guidelines on measurement uncertainty (CXG 54-2004), it is regarded positive that we want to work or propose this guideline for estimating the uncertainty of physical and chemical measurements in food, since it directs the efforts of food laboratories and enables them to work in a standardized way regarding the estimation and interpretation of the uncertainty of their results. 2. We propose to improve the initial wording of the text so that its interpretation is more user-friendly. It is important to note that the concepts are clearly explained, and the text duly provides all the necessary references so that the reader can go deeper if necessary. The examples given can be easily followed. Although it is more developed towards the top-down approach, perhaps it would be convenient to inquire a little further into the other GUM approach. 3. In relation to the terminology that should be included in Guideline CXG 54-2004, it is important to include those that are directly contained in it and allow a better understanding of the content, and in this sense, the incorporation of the definitions of the VIM is suggested. 4. Regardless of the approach for estimating measurement uncertainty, it is important at a general level to point out the steps involved in the estimation process that can be expressed in 5: Establishment of the measurement uncertainty components, assessment of the components in standard uncertainty, estimation of combined uncertainty, estimation of expanded uncertainty and measurement uncertainty report. 5. In paragraph 20 of the draft Guideline, mention is made of an Excel formula: SQRT((N-1)/CHISQ.INV(0.05,N-1); it is requested to include a mathematic formula since in this sense an excel formula is not considered advisable because this software differs formulas from one language to another and also according to their version. Similarly, it would be important to clarify this point better with an example so that it is better understood. 6. Within the guideline, it is suggested to better incorporate how the assessment of the components in standard uncertainties allows considering the estimation of the combined standard uncertainty and from this, the expanded standard uncertainty is estimated, which is the one reported in the results of food analysis, to which the guideline document refers. 7. It is necessary to include complete bibliographic references of the standards or guides mentioned in the Guideline, referring to the estimation of uncertainty of measurement and its use, for which it is suggested to include an item 31 in the document. 8. The improvement of this guideline will allow a better introduction and understanding of the estimation, use and interpretation of measurement uncertainty for food control laboratories according to ISO/IEC 17025.
Thailand General comment for draft information document on procedures for the estimation of measurement uncertainty as follow: Regarding the Sections under this information document, Thailand proposes some rearrangement for continuity and clear grouping of the text. For instance, Section 2 Top-down versus bottom-up approaches should be changed to Section 2 Approaches and under this Section separate the text into 2 sub-sections, 2.1 Top-down approach and 2.2 Bottom-up approach. In addition, to our view, Section 6 Empirical versus rational methods should come right after Section 1 Introduction, then follow by Section on Approaches and so on.
Norway We welcome the updated CXG 54 and acknowledge the impressive work laid down by Germany in preparing the new draft standard. We have the following general and specific comments to the comments at Step 6 found in CX/MAS 20/41/7 and the revised draft CXG 54 in Appendix I CL 2020/31/OCS-MAS.

General comments We support the majority of the comments in CX/MAS 20/41/7 with emphasis on shortening the document and removing redundancy in the text. Our specific comments can be found below.
New Zealand believes that the document would be more readable and easier to understand if some of the content was re-organised. We have made suggestions as to how to do this. This re-organisation will also provide for better alignment of information such as moving Section 29 to sit under 'Uses of Measurement Uncertainty'. Parts of the document reflect the on-going confusion between conformity assessment and sampling inspection. The guideline should clearly explain the differences between these activities and their use to prevent possible misapplication. NZ suggests that key points from the discussion in the paper by Holst, Thyregod & Wilrich, which provides the basis for ISO10576, should be included in the document. Reference: Holst E, Thyregod P & Wilrich P-Th (2001) On Conformity Testing and the Use of two Stage Procedures. International Statistical Review 419-432.
USP Thank you for the opportunity to comment on this work. USP very much appreciates the inclusive nature of this effort and is pleased to offer comments below.
Japan Japan appreciates the efforts of Germany in leading the electronic working group and preparing the draft revised Guidelines on measurement uncertainty. Japan will support the revised Guidelines on Measurement Uncertainty forward to STEP8 for final adoption after discussion at plenary of next CCMAS after the cooperation of the following comments below.
Peru (editorial) Throughout the document it says "tests" *(pruebas)* in some paragraphs and "essays" *(ensayos)* in other paragraphs. Prefer *ensayos* in Spanish. For the document as a whole to be consistent in its wording, the same terminology must be used in all its parts; and consider the term "essay" when referring to essays, tests, or other synonyms. Peru appreciates the work done by Germany in the revision of the Guidelines on measurement uncertainty (CXG 54-2004), which gives us the opportunity to submit the following comments. Peru has reviewed the document "DRAFT REVISION OF THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CXG 54-2004)" which considers the comments presented in Step 6 (2019) by Chile, Costa Rica, Egypt, Honduras, Iraq, Japan, Mexico, Morocco, New Zealand, Peru, Collagen Casings Trade Association (CCTA), International Commission for Uniform Methods of Sugar Analysis (ICUMSA) and The International Union of Food Science and Technology (IUFOST). Peru generally agrees with the provisions presented in the revised version of the Draft Revision of the Guidelines on Measurement Uncertainty (CXG 54-2004); with the exception of those related to numerals 9, 10 and 13 that need more consideration as highlighted in specific comments.

Iraq agree with revised draft.	
Egypt Egypt agrees the revised draft revision of (CXG 54-2004) with no comments.	
SPECIFIC COMMENTS	
Para. 1	
The results of **physical and** analytical measurements in food control are used to assess whether food products meet the relevant specifications. The accuracy of the measurement results is affected by various error components, and it is important to ensure that errors are properly considered. Since the true value of the ~~quantity~~magnitude (amount of substance) being measured is unknown, the errors cannot be known exactly. Consequently, the focus shifts to an assessment of the uncertainty associated with a measurement result. All results of ~~the~~ a measurement have an associated uncertainty; not estimating the measurement uncertainty does not mean that there is no uncertainty. ~~The estimation of this uncertainty is necessary to establish the metrological traceability of the measurement results.~~ Therefore, measurement uncertainty is of paramount importance in **physical and** analytical tests and subsequent decision making.	**Chile**
The results of **physical ~~and~~and chemical measurements corresponding to analytical ones** are used in food control to assess whether food products meet the relevant specifications. The accuracy of the measurement results is affected by various error components, and it is important to ensure that errors are properly considered. Since the true value of the quantity being measured is unknown, the errors cannot be known with accuracy. Consequently, the focus shifts to an assessment of the uncertainty associated with a measurement result. All measurement results have an associated uncertainty. Non-estimation of measurement uncertainty does not mean that there is no uncertainty. ~~The estimation of this uncertainty is necessary to establish the metrological traceability of the measurement results.~~ Therefore, measurement uncertainty is of paramount importance in **physical and** analytical tests and subsequent decision making.	**Chile**
Physical and 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~~	**Uruguay** change "Physical and analytical testing" to "testing"

~~results.~~ Accordingly, measurement uncertainty is of utmost importance in **physical and** analytical testing and subsequent decision-making.	
	Uruguay Change "physical and analytical measurement results" to "measurement results".
	Thailand We have no objection to adding "physical" before "analytical measurement". However, in our opinion "analytical measurement" generally refers to chemical methods. Therefore, to be clear and better understanding, we recommend inserting "physical and chemical measurement" instead of "physical" through the entire document, where appropriate. This sentence should be revised to read: "Physical and chemical analytical measurement results in food control are used to assess whether food products meet relevant specifications."
	Japan Para1 and throughout this document With regards to the term "Physical and analytical measurement results" or "physical and analytical testing", the term "analytical" in the existing codex guidelines always mean both physical or chemical or even biological analysis, e.g. CXG72 Guidelines on Analytical Terminology.
	Norway We understand that the sentence: "The estimation of measurement uncertainty is required to establish the metrological traceability of the measurement results." may seem confusing to readers in this paragraph. However, there are arguments to keeping this sentence in the document in order to underline the importance of measurement uncertainty. Codex standards are based on science, and metrology is "the science of measurements and its applications". Metrological traceability is defined in CXG 72-2009 "Guidelines on Analytical Terminology" as: "Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the stated measurement uncertainty." In the notes to the definition in CXG 72-2009 it is stated that: "A reference can be a definition of a

	measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard." Standardized measurement procedures (called methods in Codex) developed by standards developing organizations and endorsed by Codex are listed in Codex standards such as e.g. CXS 234 "Recommended Methods of Analysis and Sampling". Codex international food standards, guidelines and codes of practice are meant to contribute to the safety, quality and fairness of international food trade so that consumers can trust the safety and quality of the food products they buy and importers can trust that the food they ordered will be in accordance with their specifications. The Codex Procedural Manual states the purpose of Codex methods (i.e. measurement procedures) of analysis: "The methods are primarily intended as international methods for the verification of provisions in Codex standards. They should be used for reference, in calibration of methods in use or introduced for routine examination and control purposes." The CXG 83-2013 "Principles for the Use of Sampling and Testing in International Food Trade" Principle 5: Analytical measurement uncertainty states that "The selection of the product assessment procedure should take into account analytical measurement uncertainty and its implications." Measurement uncertainty has several uses such as for a meaningful comparison of measurement results as already stated in the last bullet point of Para 25 of the draft CXG 54 in Appendix I CL 2020/31/OCS-MAS. Another use of measurement uncertainty could be in the establishment of the metrological traceability of a measurement result. In order to avoid any confusion in Para 2 we therefore propose to move the sentence to Para 25 as a separate bullet point for "Uses of measurement uncertainty" instead of deleting the sentence.
Para. 2	
(editorial changes) ~~Cabe señalar que, en estas Directrices,~~ **The present document** does not provide guidance for evaluation of the contribution to total uncertainty due to sampling.	**Chile**

2. (editorial changes) **The present document** does not provide guidance for evaluation of the contribution to total uncertainty due to sampling. Likewise, it does not provide guidance on how to account for measurement uncertainty in the specification of acceptance sampling plans in connection with lot inspection.	**Honduras**
"The present document does not provide guidance for evaluation of the contribution to total uncertainty due to sampling".	**New Zealand** Suggested rewording
	Thailand This paragraph should be deleted to avoid confusion because they are the background of the document, which should not remain in the revised CXG 54-2004.
~~It should be noted that~~ **~~The present document does not provide guidance for~~** ~~, in this guideline, the evaluation of~~ **~~the contribution to total uncertainty due to~~** ~~sampling uncertainty is not included.~~	**Japan** Japan proposes to delete paragraph 2 to avoid duplication. Paragraph 5, scope, already covers the content of paragraph 2.
~~It should be noted that~~ **The present document does not provide guidance for** ~~,~~ ~~in this guideline,~~ the evaluation of **the contribution to total uncertainty due to** sampling, which can be the major component of uncertainty in the analysis of many matrices ~~uncertainty is not included.~~	**Canada**
~~The present document does not provide guidance as to how to account for measurement uncertainty in the specification of acceptance sampling plans in connection with lot inspection.~~	**Honduras**
"The present document does not provide guidance as to how to take measurement uncertainty into account in the design of acceptance sampling plans in connection with lot inspection".	**New Zealand** Suggested wording
Para. 4	
The Codex Alimentarius Commission has developed the *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods* (CXG 27-1997). It is recommended that laboratories involved in the control of food imports and exports adopt the general criteria established in the ISO/IEC 17025 [1] standard. This standard ~~requires that measurement uncertainty be included in the test report when necessary for the interpretation of test results, as appropriate. Likewise, the ISO/IEC 17025 standard establishes that the uncertainty of the measurement and its level of confidence shall be made available to the user of the results (or client), upon request. The use of measurement uncertainty must be documented to establish the rules governing decisions. In summary, the ISO/IEC 17025~~ standard requires that information regarding measurement uncertainty be ~~provided~~ included in test reports to the extent relevant to the validity or application of test results, in response to a client's request, or when the uncertainty affects compliance with a specification limit.	**Chile**

	Thailand This paragraph should be deleted to avoid confusion because they are the background of the document, which should not remain in the revised CXG 54-2004.
Scope	
Para. 5	
suggested rewording, removal of text *"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 in conformity assessment and in the design of sampling plans for the inspection of lots"*. Suggested removal of text: *"This guideline does not address the uncertainty component associated with sampling"* is repeated from section 2	**New Zealand**
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 **specifying** sampling plans **for the inspection of lots**. 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.	**Japan** The terms "in conformity assessment" in the first sentence should be deleted. According to the REP19/MAS Para63, the 40th session of CCMAS confirmed that the revised CXG 54 should not cover conformity assessment. CCMAS should be reminded the Procedural Manual (page 93, 27th edition) writes "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."
	Thailand The footnote should be removed because it is a description of "Heterogeneity" that is not related to measurement uncertainty.
Para. 6	
While the role of ~~**physical measurement**~~, **physical analysis and** chemical analysis in food control often involves quantitative analytical measurement results, qualitative results are also relevant. **While for qualitative tests an evaluation or estimation of the measurement uncertainty is not required to obtain qualitative results; however, it is suggested for the laboratories to identify the critical factors that influence the outcome of those tests and establish quality assurance mechanisms to control the relevant effects.** ~~For the estimation of the~~	**Chile**

~~measurement uncertainty associated with qualitative results, a different approach should be applied than for quantitative results~~.	
	Thailand This paragraph is a description of the evaluation or estimation of measurement uncertainty for qualitative test results. Therefore, it would be more appropriate to move this para to Introduction.
~~While the role~~ ~~of~~of Physical **measurement and** ~~chemical~~ A**analysis** ~~nalysis~~ in food control ~~often involves~~ **is often** *quantitative*~~analytical measurement results~~, **but** *qualitative* **test** results are also relevant. ~~**While an**~~ **An evaluation or estimation of measurement uncertainty is not required for qualitative results**~~**, it is recommended that laboratories identify factors which have an influence on such test results and establish quality assurance . procedures to control relevant** effects.~~For the estimation of the measurement uncertainty associated with qualitative results, a different approach should be applied than for quantitative results.~~	**Japan** The two existing Codex guideline documents has already covered quality assurance procedures: Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories (CXG 65-1997); and Food Control Laboratory Management: Recommendations (CXG 28-1995). Therefore, the revised CXG 54 should not addressed quality assurance procedure.
	Norway In order to keep the document as short as possible we do not support the proposal to include text on qualitative tests in this document. Qualitative tests would require a different approach than for quantitative test and would require its own document in order to be covered properly.
suggested inclusion of text *"Guidance on measurement uncertainty relating to qualitative results is not considered in these guidelines"*.	**New Zealand**
Prerequisites	
Para. 7	
suggested rewording of last sentence *"Furthermore, as outlined in JCGM106 and ISO10576, 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"*. **Paras 7 and 9** – comment, suggested editorial changes and inclusion of relevant references	**New Zealand**

Combine these sections and include JCGM106 and ISO10576 (and possibly other documents mentioned in the text) in the references. *"JCGM106:2012* *Evaluation of measurement data – The role of measurement uncertainty in conformity assessment* *ISO10576-1:2003 (but currently under revision)* *Statistical methods – Guidelines for the evaluation of conformity with specified requirements – Part 1: General principles"*	
Laboratories which perform ~~measurements~~ physical and chemical analysis should have effective quality assurance procedures in place (properly trained staff, maintenance and 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 ~~in chemical analysis should have effective quality 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.~~**(JGCM 106:2012 and ISO 10576).** ~~**Examples and explanations of the rules governing decisions can be found in the ISO 10576 and JGCM 106:2012 standards.**~~	**Chile**

	Thailand -This paragraph describes that the laboratories should have effective quality assurance which should be in accordance with ISO/IEC 17025. - Provided recommendation for sufficient statistical knowledge is adequate, so it is unnecessary to provide recommendations for measurement uncertainty. This paragraph should be revised to read: "Laboratories which perform physical measurements or chemical analysis should have effective quality assurance procedures in place according to ISO/IEC 17025 (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 (JCGM 106:2012 and ISO 10576)."
Terms and definitions	
For the ~~the~~ (editorial change) ~~-~~purposes of these guidelines, the terms and definitions in the following documents will apply.	**Chile**

	Thailand 1) Terms and definitions related to measurement uncertainty should be in accordance with Guidelines on Analytical Terminology (CXG 72-2009) and JCGM 200:2012 International vocabulary of metrology – Basic and general concepts and associated terms (VIM). 2) Para 9 References that are not relevant to measurement uncertainty should be deleted as the following documents since they are related to sampling, not included and mentioned in this revised CXG 54 - ISO 2859-1:2014 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 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 - ISO 6498:2012 Animal feeding stuff -- Guidelines for sample preparation - ISO 10725:2000 Acceptance sampling plans and procedures for the inspection of bulk materials 3) Para 10 - Terms and definitions for only measurement uncertainty and related terminology should be identified. The definition should be referred to as the current CXG 54-2004. However, the rest of the definition such as lot, increment, item, inspection by variables, etc. should be deleted, as they are related to sampling, and not included in the scope of this document.

	Japan Para 8, 9, 10 Regarding the terms and definitions, Japan suggests that JCGM and ISO standards list in paragraph 9 should be deleted. All necessary terms and their definitions should be stated in paragraph 10. Paragraphs 8 and 9 should be combined into one paragraph because contents of paragraph 9 is reference documents of paragraph 8. Those JCGM and ISO standards listed in paragraph 9 contains many terms. Not all terms in JCGM 200:2012 and listed ISO standards are necessary to understand the revised CXG54. There are inconsistencies between the definition of in different ISO standards. For example, in ISO 3534-2 and ISO 17025, the term "test portion" is defined as "part of a test sample which is used for testing or analysis at one time" while, in ISO 6498, the same term "test portion" is defined as "quantity of material drawn from the test sample (or from the laboratory sample if both are the same)". However, paragraph 10 only includes definition of ISO 6498. Inconsistencies of definitions also exist for terms "sample size", "sampling plan", and "item".
a. Guidelines on analytical terminology (CXG 72-2009).	**Chile**
b. JCGM 200:2012 *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM) (Vocabulario Internacional de Metrología: Conceptos básicos y generales y términos asociados).	**Chile**
	Japan If CCMAS decided to retain ISO standards, the publication year of ISO 2859-1 and ISO 3951-1 should be corrected as follows. 2014 and 2016 are years of confirmation. ISO 2859-1:1999 Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection ISO 3951-1:2013 Sampling procedures for inspection by variables – Part 1: Specification of

c. ISO 3534-1:2006 *Statistics – Vocabulary and symbols – Part 1: General statistical terms and terms used in probability* (Estadística -Vocabulario y símbolos - Parte 1: Términos estadísticos generales y términos utilizados en probabilidad).	**Chile**
d. ISO 3534-2:2006 *Statistics – Vocabulary and symbols – Part 2: Applied statistics* (Estadística -Vocabulario y símbolos -Parte 2: Estadística aplicada).	**Chile**
e. ISO 2859-1:2014 *Sampling procedures for inspection by attributes. Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection* (Procedimientos de muestreo para la inspección por atributos. Part 1: Indexed sampling plans for acceptance quality limit (AQL) for lot-by-lot inspection).	**Chile**
f. ISO 3951-1:2016 *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*. ~~(Sampling procedures for inspection by variables. Part 1: Specification of individual sampling plans indexed by Acceptance Quality Limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL).~~	**Chile**
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	**Japan**
g. ISO 6498:2012 *Animal feedingstuffs- Guidelines for sample preparation* (Piensos para animales: Directrices para la preparación de muestras).	**Chile**
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**
h. ISO 10725:2000 *Acceptance sampling plans and procedures for the inspection of bulk materials* (Planes y procedimientos de muestreo de aceptación para la inspección de productos a granel).	**Chile**
~~ISO~~ **i. ISO/IEC 17025:2017** ~~Requisitos generales~~ **General requirements for the competence of testing and calibration laboratories (Requisitos para la competencia** competencia **de los laboratorios de** ~~pruebas y calibración~~**ensayo y calibración).**	**Chile**
ISO 17025:2017 General requirements for the competence of testing and calibration laboratories	**Peru** should say: ISO 17025:2017 General requirements for the competence of testing and calibration laboratories Grounds: ISO web page https://www.iso.org/obp/ui/#iso:std:iso-iec:17025:ed-3:v2:es. For standard ISO 17025:2017 this title is considered (in Spanish translation, editorial) "General requirements for the competence of testing and calibration laboratories"

10.1. **Inspection by variables**: Inspection by measuring the magnitude of a characteristic of an element. [Quote reference]	**Chile**
~~Inspection by measuring the magnitude of a characteristic of an element.~~	**Chile**
10.2. **Increment**: Amount of material at one time from a larger quantity of product to form a sample. [Quote reference]	**Chile**
~~Amount of material at one time from a larger quantity of product to form a sample.~~	**Chile**
~~Item~~10.3. Measurand: Quantity intended to be measured [JCGM 200:2012 VIM].	**Chile**
~~Compound that can be individually described and considered.~~	**Chile**
10.4. **Laboratory sample**: Sample prepared (from the lot) for sending to the laboratory and intended for inspection or testing. [Quote reference]	**Chile**
~~Sample prepared (from the lot) for sending to the laboratory and intended for inspection or testing.~~	**Chile**
10.5. **Lot**: A lot (for the purposes of these Guidelines) is a defined quantity of a given product, manufactured or obtained under presumably uniform conditions.	**Chile**
~~A lot (for the purposes of these Guidelines) is a defined quantity of a given product, manufactured or obtained under presumably uniform conditions.~~	**Chile**
10.6. **Measurement uncertainty**: A non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used [JCGM 200: 2012 VIM].	**Chile**
Measurement uncertainty:	**Peru** should state: Measurement uncertainty A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand. Grounds: It is proposed to modify the definition of Measurement Uncertainty, in accordance with the definition stated in the ISO 21748:2017 standard "Guidance for the use of estimates of repeatability, reproducibility and accuracy in the evaluation of measurement uncertainty" and the Guide ISO/IEC 98 3: 2008 "Uncertainty of measurement - Part 3, Guide for the expression of uncertainty in measurement (GUM, 1995)"

~~Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.~~	**Chile**
10.7. **Sample**: Set of one or more items taken from a lot and intended to provide information on the lot. [Quote Reference]	**Chile**
parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand	**Uruguay** Change the definition to "non-negative parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand"
~~Set of one or more items taken from a lot and intended to provide information on the lot.~~	**Chile**
10.8. **Sampling Plan**: Specific sample size, sample selection methodology to be used and associated lot acceptability criteria. [Quote Reference]	**Chile**
Sampling Plan	**Peru** should say: Sampling plan Combination of the size of the sample or samples to be used and associated lot acceptability criteria. Grounds: It is proposed to modify the definition of Sampling Plan, in accordance with the definition set out in the ISO 2859-1 standard and considering that the sampling plan does not refer to the methodology to select the sample.
~~Specific sample size, sample selection methodology to be used and associated lot acceptability criteria.~~	**Chile**
10.9. **Sample**size Number of sample **items**. [Quote Reference]~~l~~	**Chile**
~~Number of sample items.~~	**Chile**
10.10. **Test sample**: Subsample or sample prepared from the laboratory sample and from which test portions will be taken. [Quote Reference]	**Chile**
~~Subsample or sample prepared from the laboratory sample and from which test portions will be taken. [Quote Reference]~~	**Chile**
10.11. **Analytical portion**: Quantity of material drawn from the test sample (or from the laboratory sample if both are the same). [Quote Reference]	**Chile**
~~Quantity of material drawn from the test sample (or from the laboratory sample if both are the same)~~	**Chile**
~~Sample~~10.12. Uncertainty budget: Statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination [JCGM 200:2012 VIM].	**Chile**

10.13. Expanded measurement uncertainty, U: Product of a combined standard measurement uncertainty and a factor larger than the number one. [JCGM 200:2012 VIM]. Note: normally a coverage factor k = 2 is used. 10.14. Combined standard measurement uncertainty, uc(y): Also called combined standard uncertainty or combined uncertainty, it is the standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model. [JCGM 200:2012 VIM]. 10.15 Systematic error: component of measurement error that in replicate measurements remains constant or varies in a predictable manner. [JCGM 200:2012 VIM] 10.16 Random error: component of measurement error that in replicate measurements varies in an unpredictable manner. [JCGM 200:2012 VIM] 10.17 Bias: estimate of a systematic measurement error. [JCGM 200:2012 VIM] 10.18 Coverage interval: interval containing the set of true quantity values of a measurand with a stated probability, based on the information available. [JCGM 200:2012] 10.19 Coverage probability: probability that the set of true quantity values of a measurand is contained within a specified coverage interval. [JCGM 200:2012] 10.20. Coverage factor: number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty [JCGM 200:2012]	
comment, suggested inclusion of definition Obviously definitions of these terms have still to be completed. A definition of conformity assessment should be included, we suggest:	**New Zealand** The entity could be considered as the measurand "the quantity intended to be measured" (Eurachem); a quantity that can be described by a single representing the true value, such as the true value (or level) of the sample tested or the true average level in a lot.

Conformity testing (ISO 10576-1:2003) *Conformity testing is a systematic examination of the extent to which an entity conforms to a specified criterion.* *ISO10576 continues:* *The objective is to provide assurance of conformity, either in the form of a supplier's declaration, or of a third party certification.* *A specification is usually formulated as a single limiting value, LV, or as a set of (upper and lower) limiting values for a measurable characteristic. When the specification refers, e.g. to health-related characteristics, the limiting values are sometimes termed threshold limit value TLV, or permissible exposure limits, PEL.*	
General considerations	
Para. 12	
Measurements are affected by many factors such as effects related to changes in temperature, pressure, humidity, matrix variability, or the analyst's ~~valuation~~ repeatability. These errors can be classified as *systematic* or *random*. Systematic or random errors are components of measurement uncertainty. The term *bias* is often used to refer to a systematic error. Although all components of *systematic error* could be evaluated and corrected, the measurement results would still be subject to *random errors* that cannot be corrected, which would result in an uncertainty interval. An example of the way in which a random error is manifested is the dispersion of the results of the observed measurement when the measurements are made in a laboratory under almost identical conditions, that is, in repeatable conditions. **Both systematic and random measurement uncertainty components, respectively, should be quantified in a summarized manner.** ~~The different components of measurement uncertainty must be determined and estimated. Some of them~~ **The different components of measurement uncertainty** can be evaluated from the statistical distribution of the results of a series of measurements and characterized by typical standard	**Chile**

deviations. The other ~~items~~ **components**, which can also be characterized by typical standard deviations, are evaluated from supposed distributions derived from experience or other information. All components of uncertainty, including those derived from systematic effects such as uncertainty of bias adjustments and reference standards, contribute to dispersion.	
Para. 11	
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 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.	**Thailand** The sentence: "It is assumed that any necessary bias correction has been correctly performed." should be retained.
Para. 13	
It is important to note that 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. **However, it is of utmost importance to identify and evaluate the systematic components of measurement uncertainty, as these cannot be reduced by repeated measurements. Whenever possible, test methods that have been validated by collaborative studies should be used. In case there are two methods with the same measurement uncertainty, the method with the lowest systematic error should be preferred.**	**Peru** It is suggested to remove the paragraph. Grounds: Systematic errors are not only associated with the method, but also with the matrix, equipment, personnel, etc. Identification of systematic components and a joint (global) assessment of bias (if possible) are sufficient. The lack of CRM does not allow in many cases an estimation of bias.
	Thailand This paragraph should be revised as follows: "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 contributing to a measurement uncertainty range."
	Thailand This paragraph should be revised to read: "However it is for utmost importance to identify and evaluate systematic components of measurement uncertainty where applicable since these cannot be reduced by repeated measurements. Whenever possible test methods should be used that have been validated by collaborative studies. In case that

	there are two methods with identical measurement uncertainty, the method with lower systematic error should be preferred."
Paras 12 and 13 Several sections go into some detail about components of measurement uncertainty – we suggest that some rationalisation of the document could occur. Measurement uncertainty is understood as being a measure, expressed as a standard deviation, of the random components of measurement error; it is not clear what is meant by "systematic components of measurement uncertainty". There are more fundamental effects such as [small, random] errors in weighing, scale resolution, judging end points of titrations etc. that may contribute to measurement error other than those listed. We sense some conflicting advice between sections 12, 13 and 14; section 12 and 14 suggests that all components should be evaluated whereas section 13 says only the main components might be evaluated.	**New Zealand**
Uncertainty components	
Para. 14	
When making a measurement, it is important to consider all possible components of uncertainty that will influence the outcome. The ~~The~~sources of typical components of uncertainty include the effects associated with the instruments, the analyst, the sample matrix, the method, the calibration, the time and the ~~environment~~ (environmental conditions). These sources may not be independent, in which case the respective correlations must be taken into account in the calculation of uncertainty, that is, in the estimation of total uncertainty. In addition, in certain circumstances, the effect associated with a certain uncertainty component may change over time and, consequently, a new estimate of the measurement uncertainty may be necessary. For more information on this subject, please refer to the CG 4 EURACHEM/CITAC Guide.	**Chile**
suggested rewording The *"uncertainty budget"* should be mentioned in the first sentence - it is an important concept. We suggest:	**New Zealand**

When performing a measurement, it is important to consider the contribution of all possible uncertainty components which will influence the result of the measurement to the uncertainty budget.	
Procedures for estimating measurement uncertainty	
Para. 15	
There are many ~~procedures~~ **approaches** 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]. **Among these scientifically acceptable approaches, none can be ranked better than any other, meaning that there is no "hierarchy" between such approaches.** The choice of the appropriate ~~procedure~~ **approach** depends on the type of **measurement** or analysis, the method used, the level of reliability confidence required and the urgency of the request for an estimate of the 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~~ studies, proficiency ~~studies~~ tests, validation studies or intra-laboratory quality control samples, or a combination of such data.	**Honduras**
There are many ~~procedures~~ **approaches** 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]. **Among these scientifically acceptable approaches, none can be ranked better than any other, meaning that there is no "hierarchy" between such approaches.** The choice of the appropriate ~~procedure~~ **approach** depends on the type of **measurement** or analysis, the method used, the level of reliability confidence required and the urgency of the request for an estimate of the measurement uncertainty. In general, procedures are based either on a "bottom-up" or component by component approach or on a "top-down" approach, with the latter using data from collaborative ~~trials~~ **studies**, proficiency studies tests, validation studies ~~or~~ intra-laboratory quality control samples, or a combination of such data~~.~~ Regardless of the uncertainty approach, in general the following procedure should be established for its determination, indicated in figure 1: General steps for Estimating Measurement Uncertainty (1) Establishing uncertainty components (2) Estimating and expressing standard uncertainty component (3) Estimating combined uncertainty	**Chile**

(4) Estimating expanded uncertainty (5) Reporting the measurement uncertainty of a result *This chart is in a figure that can't be pasted in this format	
	Thailand To be clear and avoid confusion, the use of word "approach" and "procedure" in this section should be reviewed according to their objectives and intention of each content. Additional sentence: "Among such scientifically acceptable approaches, none may be said to be better than any other – i.e. there is no "hierarchy" among such approaches" should not be added to this paragraph, since the current text is appropriate, meanwhile the additional sentence does not provide any further description.
	Norway We support to keep the documents mentioned in the text since they provide a reference for further information for the reader.
Para. 16	
suggested alteration of text It is not necessary to mention the *"target reproducibility"* as it is not needed for the estimation of MU, the analysis of proficiency testing data is essentially the same as for inter-laboratory validation studies.	**New Zealand**
16.1. Modelling (classical ISO and GUM)	**Chile**
	Japan Para 15, 16 "ISO GUM" in paragraph 16 should be corrected to "ISO/IEC Guide 98-3:2008" for consistency if it refers to the same guidance document "ISO/IEC Guide 98-3:2008" in paragraph 15.
Bottom-up component-by-component evaluation according to ISO ~~GUM~~and GUM standard based on measurement model.	**Chile**
Modelling ~~(Classical ISO GUM)~~ (ISO/IEC Guide 98-3:2008)	**Japan**
16.2. Single-lab validation	**Chile**

Bottom-up component-by-component evaluation according to ~~ISO GUM~~ISO/IEC Guide 98-3:2008	**Japan**
Top-down approach e.g. according to Nordtest TR 537, NMKL procedure No. 5, EURACHEM/~~CITAC Guide CG 4 (uncertainty~~ CITAC, that is uncertainty of results obtained using the same procedure in a single laboratory and in varying conditions as described ~~above)~~above.	**Chile**
16.3. Interlaboratory validation	**Chile**
Top-down approach using the reproducibility standard deviation (**ISO 5725** and ISO 21748) ~~(uncertainty~~ that is, uncertainty of results obtained using the same procedure in different ~~laboratories)~~laboratories.	**Chile**
16.4. Proficiency testing (PT)	**Chile**
– Top-down approach using the reproducibility standard deviation (**ISO 5725 and** ISO 21748) (uncertainty of results obtained using the same procedure in different laboratories)	**Norway** We do not support the inclusion of ISO 5725 since this document is regarding accuracy (trueness and precision) of methods and because ISO 21748 already covers the use of precision and trueness estimates in measurement uncertainty.
Top-down approach using the target reproducibility standard deviation (~~target uncertainty~~, that is uncertainty of results obtained by analysing the same samples in different ~~laboratories)~~laboratories.	**Chile**
Para. 17	
These procedures are not equivalent and can give rise to different estimates of measurement uncertainty. In the top-down approach, the standard deviation of reproducibility obtained from collaborative studies is often used as ~~a calculation~~ **an estimate** of measurement uncertainty. The uncertainty component of the matrix mismatch must be properly taken into account when estimating the uncertainty of the measurement. To overcome this deficiency, different matrices and concentration levels can be used, depending on the scope of the method. In the case of a validation study made in a single laboratory, an intermediate precision (reproducibility within the laboratory) is used to estimate uncertainty and, therefore, laboratory bias is lacking, resulting in that the uncertainty may have been underestimated. As a consequence of the above, with the result that the uncertainty obtained may have been underestimated. Depending on the case, this can be addressed, for example, by estimating and correcting the bias through a recovery experiment (with due regard to the "uncertainty of the recovery correction in the combined uncertainty or by simulating the laboratory bias by varying the effects that could affect, for example, analytical instruments, analysts, time period, sample preparation equipment, etc. **Certified reference materials can also be used to estimate bias and its uncertainty.**	**Chile**

These procedures may vary with regard to the influencing effects included there is also often considerable variation due to random variability of the standard deviation figures (intermediate precision, ~~precision [within-lab reproducibility] intermediate~~), reproducibility, repeatability). Therefore, both the chosen approach for estimating measurement uncertainty (in-house validation, collaborative study, bottom-up approach etc.) and the estimated level of confidence of the measurement uncertainty should be provided.	**Chile**
	Thailand To be clear, the last sentence should be revised to read: "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 total uncertainty) or by simulating the laboratory bias by varying influencing effects like analytical instruments, analysts, time span, equipment for sample preparation, etc. Where possible, Certified reference materials can also should be used to estimate bias and its uncertainty."
Para. 19	
Almost all uncertainty data are expressed as standard deviations or functions of standard deviations. If a standard deviation is calculated using a small amount of data, ~~there is~~ producing an overestimate of the ~~considerable~~ uncertainty in the estimate of measurement uncertainty obtained.	**Chile**
Para. 19	
suggested rewording Include under reporting in uses of MU. The term *"Functions of standard deviations"* seems excessive, this concept could be expressed more simply by saying *"on an absolute or relative basis, relative to the average level"*. This will cover the majority of cases encountered in practice. The second sentence should be reworded *"There is often considerable uncertainty of estimated standard deviations…"*. This uncertainty is addressed when calculating the expanded uncertainties (Section 20).	**New Zealand**
Para. 20	
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	**Chile**

laboratories each with a single measurement, the true standard deviation can be up to 2-3 times the estimated standard deviation. Under these conditions, the true standard deviation can be calculated using a multiplication factor f that relates the estimated and true values as a function of the number of measurements. For more information on the application of this factor and the formulas for calculating the true standard deviation, refer to the document Guidelines on Estimation of Uncertainty of Results CXG 59-2006. **This exact factor by which the estimate should be multiplied,** can be calculated with the following Excel formula: SQRT((N-1)/CHISQ.INV(0.05,N-1)**), where N is the number of laboratories or the number of tests within a single laboratory.** ~~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. Factor,f=√(n-1)/(inv-X^2(alfa =0,05;n-1) Where: n: the number of laboratories or the number of tests within a single laboratory. inv-X^2(alfa=0.05:n-1): Inverted X square for n-1 degrees of freedom for 95% confidence. Using for example in Excel the formula: SQRT((N-1)/CHISQ.INV(0.05,N-1)), where N is the number of laboratories or the number of tests within a single laboratory [indicate Excel version for this formula]. 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.	
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. **The exact** factor **by which the estimate should be multiplied** can be calculated with the following Excel formula: SQRT((N-1)/CHISQ.INV(0.05,N-1**)), where N is the number of laboratories or the number of tests inside the single laboratory.** The~~is uncertainty~~ **reliability** of measurement uncertainty components should be taken into account in the design of experimental studies and the evaluation of measurement uncertainty.	**Thailand** This paragraph should be removed since it is already explained in Section 8 in the Information Document.
suggested inclusion of text and relocation	**New Zealand**

Replace *"exact factor"* by the "*coverage factor*".	There is possible confusion here, the document does not make it clear that to calculate 95% confidence intervals one can either (a) apply the correction based on the chi-squared distribution and then use a coverage factor of k = 2 or (b) use a coverage factor based on the 95% percentile of the t-distribution. Apart from the last sentence, this section could be included in the reporting section or after Section 25. The last sentence relates to the estimation of measurement uncertainty and should be moved to Section 16.
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. **The exact** factor **by which the estimate should be multiplied** can be calculated with the following Excel formula: SQRT((N-1)/CHISQ.INV(0.05,N-1**)), where N is the number of laboratories or the number of tests inside the single laboratory.** The~~is uncertainty~~ **reliability** of measurement uncertainty components should be taken into account in the design of experimental studies and the evaluation of measurement uncertainty.	**Norway** The syntax of the formula may vary between different setups of Excel (e.g. language and comma separator) and this should be notified to the reader in a footnote.
	Canada Suggest having a clearer connection to measurement uncertainty. The two bullet points have resulted in confusion to some readers: a. as stating that the aspects of the method that contribute the most to measurement uncertainty are to have limits. It is not clear if the point is suggesting that these major components contributing the most to measurement uncertainty are to be monitored and kept within the set limits. There is no connection to measurement uncertainty in point b.
	Thailand This sub-section should be revised to read: "a. the laboratory uses a validated in-house test method with established limits regarding the major measurement uncertainty components along with the exact manner in which relevant quantities must be calculated"
Para. 21	
It is recommended that laboratories performing food analysis with quantitative methods always evaluate the measurement uncertainty. ~~, In cases where a~~	**Chile**

~~rigorous evaluation cannot be made~~ **Even if some components of measurement uncertainty cannot be assessed,** ~~evaluated, estimation of measurement uncertainty should at least can be estimated done,~~ **frequently these components can be at least 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. Once the uncertainty components have been evaluated and defined, the combined measurement uncertainty will be estimated, according to the "Rule of propagation of uncertainties". Subsequently, the expanded measurement uncertainty U must be estimated, which is obtained by multiplying the combined standard uncertainty uc (y) by a coverage factor k. The value of the coverage factor is based on the required level of confidence, frequently 95% is used whose value of k = 2, in the case of a normal (Gaussian) distribution: U = k x uc(y) 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 relevant factor of the Student distribution.	
Para. 23	
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~~described above, 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.	**Chile**
Paras 22 and 23 suggested relocation These sections could be included under "Assessing Laboratory Performance" in Section 25 on the uses of MU.	**New Zealand**
suggested relocation This appears a little out of place, possibly better relocated to precede Section 15	**New Zealand**
Para. 24	
~~The *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods* (CXG 27-1997)~~ **ISO/IEC 17025**	**Honduras**

requires laboratories involved in the import and export of food to ~~meet the general criteria established in standard ISO/IEC 17025. This standard requires laboratories~~ use validated methods; therefore, ~~it is usually advisable to use~~ **the** data from the validation study **performed in several** laboratories or in a single laboratory **could be used to estimate measurement uncertainty after, ~~the top-down approach~~ with a top-down approach.**~~, instead of another approach such as the bottom-up approach top-down approach.~~ Section 7.6.2 of the CG 4 EURACHEM/CITAC Guide provides a procedure to assess measurement uncertainty using data of ~~joint~~ **collaborative** studies. In Guide CG 4 EURACHEM/CITAC, reference is also made to the ISO 21748 standard as the main source for the estimation of uncertainty based on "data from collaborative studies obtained in accordance with the ISO 5725 standard".	
. In the Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food (CXG 27-1997) a requirement for control laboratories involved in the import/export of foods is to comply with the requirements set forth in ISO/IEC 17025. In this context, laboratories are required to use validated methods; therefore, the data from the validation study performed in several laboratories or in a single laboratory could be used to estimate measurement uncertainty after the top-down approach. ~~In the *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods* (CXG 27-1997) **ISO/IEC 17025** there is a requirement for the laboratories involved in the import and export of food to meet the general criteria established in standard ISO/IEC 17025. This standard requires laboratories to use validated methods; therefore, it is usually advisable to use **the** data from the validation study **performed in several** laboratories or in a single laboratory **could be used to estimate measurement uncertainty after the top-down approach.**~~, ~~instead of another approach such as the bottom-up approach.~~ Section 7.6.2 of the CG 4 EURACHEM/CITAC Guide provides a procedure to assess measurement uncertainty using data of joint studies. In Guide CG 4 EURACHEM/CITAC, reference is also made to the ISO 21748 standard as the main source for the estimation of uncertainty based on "data from collaborative studies obtained in accordance with the ISO 5725 standard". Issued outcome reports and/or certificates should comply with ISO/IEC 17025.	**Chile**
ISO/IEC 17025 ~~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~~	**Uruguay** change the text "requires laboratories involved in the import/export of foods to use validated methods" to "requires laboratories to use confirmed/validated methods"

~~the bottom-up approach~~ **can be used for the estimation of measurement uncertainty following the top-down approach.** In Section 7.6.2 of the EURACHEM / CITAC Guide CG 4 ~~EURACHEM / CITAC Guide CG 4~~, a procedure for evaluating measurement uncertainty using collaborative study data is provided. The EURACHEM / CITAC Guide CG 4 ~~EURACHEM / CITAC Guide CG~~ 4also 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".	
~~**ISO/IEC 17025** The *Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food* (CXG 27-1997)~~ 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~~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~~ **can be used for the estimation of measurement uncertainty following the top-down approach.** In Section 7.6.2 of the EURACHEM / CITAC Guide CG 4 ~~EURACHEM / CITAC Guide CG 4~~, a procedure for evaluating measurement uncertainty using collaborative study data is provided. The EURACHEM / CITAC Guide CG 4 ~~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** Japan proposes to retain original first sentence because of the following reasons: 1) CXG 27-1997 is a Codex guideline; and 2) CXG 27 includes ISO/IEC 17025 but also implementation of quality assurance using validated methods.
Uses of measurement uncertainty	
comment, suggested restructuring and rewording Uses of Measurement Uncertainty This section contains some detail for each of the possible uses with more discussion on reporting and conformity assessment in other sections. Suggest using Section 25 to list only the possible uses then include subsections dealing with each use in more detail. 1. Reporting There is an issue here relating to the comment on Section 20 above and this topic is also discussed in sections 26 and 27. The correct terminology is "*Student's t-distribution*". 2. Conformity Assessment This text could be rationalised by including the definition of Conformity Assessment in Section 9.	**New Zealand**

3. For the design of acceptance sampling plans based on inspection by variables. The determination of the sample size and acceptability constant for inspection by variables plans when the measurement uncertainty is large in relation to the process standard deviation (i.e. significant) is based on the procedures and the sampling plans provided in ISO standards e.g. ISO 3951 Part 1 Annex O and Part 6 and in the Codex Guidelines for Sampling GL50. 4. For the characterization of certified reference materials 5. For comparisons between measurement results Between measurement results and true/reference values or between different sets of measurement results produced say, by different laboratories (ISO 5725-6). Could also refer to the Codex Guidelines for Settling Disputes over Analytical (Test) Results CXG70-2009.	
a. Notification of measurement results (see ISO/IEC 17025)~~:~~. In general, the measurement uncertainty is reported as expanded (editorial change) uncertainty of the measurement.	**Chile**
~~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.~~	**Chile**
• Reporting of measurement results (see ISO/IEC 17025):	**Thailand** This bullet should be revised to read: "• Reporting of measurement results (see ISO/IEC 17025): Typically, the measurement uncertainty is reported as the expanded measurement uncertainty , i.e. as the standard uncertainty multiplied by a coverage factor = 2, which for a normal (Gaussian) distribution corresponds to a coverage probability level of confidences of approximately 95 %.
For conformity assessment, to assess whether the true value of the tested sample ~~conforms~~ conforms (editorial change) to the specification (see paragraphs 26 and 27). This is different from sampling inspection where	**Honduras**

acceptance or rejection of a lot is assessed. Examples and explanatory notes may be found in JCGM 106:2012 and ISO 10576.	
b.**For conformity assessment, to assess whether the true value of the tested sample ~~conforms~~ conforms or does not conform to the specification (see paragraphs 26 and 27). This is different from sampling inspection where acceptance or rejection of a lot is assessed. Examples and explanatory notes may be found in JCGM 106:2012 and ISO 10576**.	**Chile**
	Uruguay change "to a coverage probability of 95.45 %"
c.Assessing the performance ~~performance~~ (editorial change) of laboratories (see ISO 13528).	**Chile**
• **For conformity assessment, to assess whether the true value of the tested sample complies with a specification (see paragraphs 26 and 27). This is different from sampling inspection where the conformity of a lot is assessed. Examples and explanations of decision rules can be found in JCGM 106:2012 and ISO 10576.**	**Thailand** This bullet should be revised to read: "• For conformity assessment to assess whether the true value of the tested sample complies with a specification (see paragraphs 26 and 27). This is different from sampling inspection where the conformity of a lot is assessed. conforms to a specification limit. The assessment needs a decision rule which takes into account measurement uncertainty. Examples and explanations of decision rules can be found in …."
~~**For conformity assessment, to assess whether the true value of the tested sample complies with a specification (see paragraphs 26 and 27). This is different from sampling inspection where the conformity of a lot is assessed. Examples and explanations of decision rules can be found in JCGM 106:2012 and ISO 10576.**~~	**Japan** The second bullet should be deleted because the 40th session of CCMAS already agreed that the revised CXG 54 does not cover conformity assessment (REP19/MAS, Para63).
For the design of acceptance sampling plans based on inspection by variables. ~~(see ISO 3951 standard and CXG 50 Guidelines):~~	**Chile**
~~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 **(for instance, ISO 3951 and GL50). When the measurement uncertainty is large relative to the standard deviation process, it must be taken into account in these calculations.** This calculation has to take into account the components of measurement uncertainty.~~	**Chile**
e.**To characterize ~~certified~~ certified reference materials (ISO Guide 35).**	**Chile**
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	**Japan** In the fifth bullet, Japan proposes the following: 1) The last sentence should be deleted because importing and

and/or Codex guidelines **(e.g. ISO 3951 and ~~GL50)~~CXG50).** ~~**When large in relation to the process standard deviation, measurement uncertainty should be taken into consideration in these**~~ ~~This calculation has to take into account the components of measurement uncertainty.~~	exporting governments usually do not know process standard deviation. Importing governments use only analytical result of the target lot for inspection for making judgement. Process standard deviation can be monitored by food manufacturers. 2) "GL50" should be "CXG 50".
f.**For t**~~T~~he comparison between measurement results and true or reference values (ISO 5725-6).	**Chile**
• **For the characterization of certified reference materials**	**Thailand** For consistency through the whole document, "see ISO/IEC 17034" should be added at the end of the bullet. So, this bullet should be read: "• For the characterization of certified reference materials (see ISO 17034)
How to report measurement uncertainty in test results	
In accordance with ISO/IEC 17025 measurement uncertainty should be reported to allow for a decision as to whether *a laboratory sample* meets a specification on the basis of an analytical result. . The result of a measurement is conveniently expressed as: Y = y ± U Its interpretation means that the best estimate of the value attributable to the measurand Y is y, and that y - U to y + U is an interval that is expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand.	**Chile**
suggested rewording Change title of sub-section from *"How to Report measurement uncertainty…"* to *"Reporting Measurement Uncertainty"*.	**New Zealand**
	Thailand Para. 26 should be deleted due to duplication with bullet 2, Para 25.
~~In accordance with ISO/IEC 17025~~ The measurement uncertainty ~~should~~ and its level of confidence should, on request, be ~~reported~~ made available to ~~allow for a decision as to whether a~~ the user (customer) of the results.~~*laboratory sample* meets a specification on the basis of an analytical result.~~	**Japan** Japan proposes that paragraph 26 should be replaced with the 3rd recommendation of the existing CXG54 for user friendliness and for consistency with the title of this section "How to report measurement uncertainty in test results". Confidence level of measurement uncertainty should be reported because paragraph 25 refers to the coverage factor. It is also needed to clarify to

	whom to report. Although original paragraph 26 suggests the reason for reporting measurement uncertainty, it did not indicate what kind of information should be reported, nor to whom to report.
Suggest change of wording to add clarity, inclusion of text *"In ISO/IEC 17025 measurement uncertainty should be reported to allow for a decision whether the true value of a laboratory sample meets a specification on the basis of an analytical result"*. We recommend that the caveat, that conformity assessment cannot be used as a **valid lot assessment procedure**, currently appearing in Sections 25, 28 and 29 is included here and we suggest the following: *"However conformity (or non-conformity) of the true value of a sample does not necessarily mean that a lot is compliant (or non-compliant).* *For example, while non-conformity of a sample tested for pesticides or other serious food-safety parameters would be interpreted as non-compliance of the lot this interpretation is not true in general, a lot might be of acceptable quality even though samples are non-conforming. The converse is also not true; conformity of a sample does not necessarily mean compliance of a lot. Use of conformity assessment procedures for lot inspection will not provide assurance to consumers that product is of acceptable quality, the principal objective of acceptance sampling"*.	**New Zealand**
While desirable, reporting whether a bias correction has been applied is outside the scope of measurement uncertainty. We presume the reference to the Procedural Manual refers to the section on the "Use of Analytical Results", however this section is quite sketchy. A more specific reference should be provided.	**New Zealand**
The~~However, the~~ The ISO/IEC 17025 standard **does not specify exactly what information must be reported**. ~~It establishes how the uncertainty in measurement should be taken into account.~~ ~~It is clear, however~~ However, ~~that~~ **it would be useful to include information** ~~It is not enough to consider only the uncertainty of measurement, but it is necessary to include information~~ ~~about~~ (editorial change) about whether a correction to the ~~the~~ bias of the method has been applied, ~~(if significant)~~ and if the contribution corresponding to the uncertainty of the correction of the bias ~~of the uncertainty~~ **is included in the reported measurement uncertainty.** ~~On whether or not a correction was applied to the reported measurement uncertainty~~. **The reader is also referred to the relevant sections**	**Chile**

in the Codex Alimentarius Commission Procedural Manual (27th Edition, 2019).	
However, ISO/IEC 17025 does not ~~state~~**specify exactly which information should be reported**. ~~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~~ **would be useful** to include information ~~on~~ **as to whether a correction for method bias was applied and whether the contribution corresponding to uncertainty of bias correction is included in the reported measurement uncertainty**~~and on whether or not a correction was applied.~~ **The reader is also referred to the relevant sections in the Codex Alimentarius Commission's Procedural Manual (27th edition, 2019).**	**Thailand** The last sentence refers to the relevant sections in the Procedural Manual, thus those sections should be clearly specified in this paragraph.
suggested rewording, inclusion of text Replace sub-heading *"Examples of situations…"* by *"Conformity Assessment"*	**New Zealand**
Examples of situations occurring when measurement uncertainty is considered	
~~**Examples of situations**~~ **Situations occurring when measurement uncertainty is considered - 4 cases**	**Chile**
	Uruguay In the section "Examples of situations occurring when measurement uncertainty is considered" take into consideration the use of guard bands as described in ILAC G8:2019 (https://ilac.org/publications-and-resources/ilac-guidance-series). So the decision whether the laboratory sample meets the specification or not depends on the rules which the different parties involved have agreed to apply including the police related with the guard band. Change paragraph 29, taking into account pictures and texts from the ILAC G8:2019.
suggested restructuring and rewording We suggest including material from paras 28 and 29 suitably reworded to reflect that Figure 1 does represent a valid conformity assessment procedure. However other procedures are available, ISO10576 employs two stage conformity assessment procedure and approaches based on the probability that the true value exceeds the limit or using the Fractional Non-Conformance methodology can be used. The caveat, that conformity assessment cannot be used as a **valid lot assessment procedure**, is repeated.	**New Zealand**

28. ~~The following~~ Figure 1 illustrates how the measurement uncertainty can affect decisions about whether or not the true values of a **tested** (editorial change) **sample** conform to the limits of the specification. ~~However, this~~ Figure 1 is provided **only** to illustrate the principle. Measurement uncertainty intervals, such as those in Figure 1, cannot be used as a valid ~~product~~ **conformity** evaluation procedure.	**Chile**
~~The~~Figure 1~~below~~ illustrates how measurement uncertainty can affect decisions whether the true values **of the samples tested** conform to specification limits. ~~However~~ **Figure 1 is intended to illustrate the basic principle only.**~~ve purposes of the principle~~ Measurement uncertainty intervals such as those in Figure 1 cannot be used as a valid ~~product~~**conformity** assessment procedure.	**Thailand** For better understanding, this paragraph should be revised to read: "Figure 1 illustrates how measurement uncertainty can affect decisions whether the true values of the samples tested conform to specification limits. Figure 1 This figure is intended to illustrate the basic principle only. Measurement uncertainty intervals such as those in Figure 1 cannot be used as a valid conformity assessment procedure."
Suggested rewording: More precise wording should be used for describing the interpretation of the outcomes shown in the diagram, replacing "it" by "*the true value (or level) in the sample (or entity)*"	**New Zealand** CXG 83-2013 "Principles for the Use of Sampling and Testing in International Food Trade" recommends 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" prior to the commencement of trade.
29. The actual decision whether the *laboratory sample* meets the specification or not depends on the rules which the different parties involved have agreed to apply. 30. ISO/IEC 17025 requires laboratories to assess uncertainty of measurement and to apply a documented decision rule when establishing statements of conformity.	**Chile**
Figure ~~1~~2: How to take 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 (y) and the vertical bar represents the associated measurement uncertainty interval (that is expanded uncertainty; y +- U).	**Chile**
The analytical result minus the expanded (editorial change) measurement uncertainty exceeds the maximum level. The conclusion is that it lies above the specification.	**Chile**

Situation i	
Situation i The analytical result exceeds the maximum level by more than the expanded measurement uncertainty. The conclusion is that *the true value or level in the sample* lies above the *maximum, with the stated level of confidence*.	**New Zealand**
The analytical result differs from the maximum level to a lesser extent than the expanded (editorial change) measurement uncertainty. The standard interpretation here is that the outcome is inconclusive, that is, doubtful. Action on this result depends on existing agreements between the trading partners.	**Chile**
Situations ii and iii The analytical result differs from the maximum level by less than the expanded measurement uncertainty. The *accepted* interpretation is *that* the outcome is inconclusive. Action on this *outcome* depends on existing agreements between the trading partners.	**New Zealand**
Situation iv	
The result of the analysis is lower than the maximum level to a greater extent than the value of the ~~extended~~ extended (editorial change) uncertainty of the measurement. The decision is that it lies below the specification.	**Chile**
The analytical result is *less than* the maximum level by more than the expanded measurement uncertainty. The decision is that *the true value or level in the sample* lies *within the* specification limit, *with the stated level of confidence*. Note: The measurement uncertainty interval in Figure 1 and its comparison to the maximum level relates to Conformity Assessment, whether the true values of the samples tested comply with the maximum limit *and should not be used* for lot acceptance.	**New Zealand** Final paragraph - the highlighted text below suggests conformity assessment is used for the inspection of trade consignments against the strong advice in the caveat. *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* ***or maximum level*** *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".
Note 31. REFERENCES: 31.1. JCGM 200:2012 International vocabulary of metrology – Basic and general concepts and associated terms (VIM) (Vocabulario Internacional de Metrología: Conceptos básicos y generales y términos asociados). 31.2. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories 31.3. Nordtest TR 537, Handbook for calculation of measurement uncertainty in environmental laboratories. 31.4. NMKL Procedure No.5, Estimation and expression of measurement uncertainty in chemical analysis. 31.5. CITAC Guide number 4, EURACHEM/CITAC Guide Quantifying Uncertainty in Analytical Measurement. 31.6. Eurachem/CITAC Guide: Setting and Using Target Uncertainty in Chemical Measurement. 31.7. JCGM 100:2008 GUM Evaluation of measurement data — Guide to the expression of uncertainty in measurement. 31.8. ISO 5725-2:2019 Accuracy (trueness and precision) of measurement methods and results. 31.9. ISO 21748:2017 Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation.	**Chile**

	Canada Suggest revising in the last "Note" **"exporting country" and "importing country" to "exporter" and "importer",** respectively, to be more inclusive. Transactions do not occur between "countries" exclusively, companies also conduct international trade. This document is thought to be used by individuals involved in international trade, not strictly governments.