codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

**Agenda Item 3b)** **CX/MAS 06/27/4**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING**
**Twenty-seventh Session**
**Budapest, Hungary, 15-19 May 2006**

# PROPOSED DRAFT GUIDELINES FOR SETTLING DISPUTES OVER ANALYTICAL (TEST) RESULTS

## GOVERNMENT COMMENTS AT STEP 3
## (Argentina, Australia, European Community, Japan, Malaysia, New Zealand)

**ARGENTINA**
**English version**

Argentina wishes to propose the following amendments to the text, which are marked by text in bold.

**PREREQUISITES:**

Laboratories should comply with quality assurance provisions and with the *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and the Export of Food (CAC-GL 27-1997)* **and their updates**; and

**3.1. – STEP 1**

When the results are within the reproductbility limit the mean should be used to assess conformity, taking into account measurement uncertainty **(GUIDELINES: ILAC-G8/1996, INTERNATIONAL LABORATORY ACCREDITATION COOPERATION).**. When results are outside the reproductibility limit, the comparison concerns **the requirements established in 5.4.5.2 and 5.9 of the most recent version of standard ISO/ IEC 17025, considering at least**:

**ARGENTINA**
**Versión en español**

Argentina agradece la posibilidad de realizar comentarios al presente documento.

Argentina desea proponer las siguientes modificaciones al texto, las cuales se destacan en negrita.

Requisitos previos

Los laboratorios deben cumplir con controles de aseguramiento de la calidad en acuerdo a la *Guía de Evaluación de la Competencia de los Laboratorios de Ensayos involucrados en la importación y exportación de alimentos (CAC-CL 27-1997* **y sus actualizaciones**) y

Punto 3.1 Etapa l

Cuando los resultados están dentro del límite de reproducibilidad la media debe usarse para evaluar la conformidad, tomando en cuenta la medida de la incertidumbre **(GUIA:ILAC-G8/1996, INTERNATIONAL LABORATORY ACCREDITATION COOPERATION).** Cuando los resultados están fuera del límite de reproducibilidad, corresponde considerar **los requisitos establecidos en los puntos 5.4.5.2 y 5.9 de la última versión de la Norma ISO/IEC 17025 contemplando como mínimo:**

## AUSTRALIA

### General Comments

Australia supports the need for general guidance for the Codex community on settling disputes over analytical (test) results, particularly as such guidelines would ensure an improved understanding of potential limitations of such disputes. However, in order to provide useful guidance consistent with current practices, significant improvements to the document are still required. Australia's primary concern is that the draft guidelines could create confusion regarding the role of the laboratory as the responsible body for settling disputes over analytical (test) results. Although there is no doubt about the involvement of laboratories in assisting with dispute resolution where appropriate, the guidelines should clearly and consistently reflect that it is the role of the regulatory/ enforcement body responsible for interpretation of test results or a (nominated) third party to undertake steps towards dispute resolution over analytical (test) results. It is particularly important for clarification of the requirement for retest on "common" and "reserve" samples. Unless laboratories are retesting *identical* samples it is unlikely that disputes over analytical test results will be resolved effectively. Furthermore, there may be situations where it is agreed that dispute settlement over analytical results using steps 2-3 may not be applicable. These situations should be identified in the guidelines.

### Specific Comments

### 2. Prerequisites

Australia suggests that the second dot point be amended to read:
"one representative analytical sample from the same product lot should be taken in accordance with established sampling plans and/or good sampling practices, where applicable; the analytical sample should be split for the purposes of analysis and for confirmatory analysis; the retained portion of the analytical sample should be kept in a satisfactory condition for the appropriate length of time".

The document provides no agreed definition of the "representative analytical sample." Australia suggests that the document incorporates a definition such as "representative analytical sample" means the remaining component of sample used for the purposes of providing the original (disputed) test result.

It is unclear who would keep the sample in a satisfactory condition for an appropriate length of time. Specific parameters such as the shelf life of the product or the time necessary for carrying out commercial transactions are highly variable parameters and most laboratories would have constraints on their understanding of various product shelf lives and more importantly from a practical perspective on the available storage space for samples. It may be simpler to clarify what "an appropriate length of time" is for the retained portion of the representative analytical sample in approximate terms i.e. 30 days. If the wording implies that importers should hold a representative sample from the split, it should be recognised that not all member countries provide opportunities for importer involvement in sampling and that unless the same sample (representative analytical sample as defined earlier) is being re-analysed it is difficult to disprove the veracity of the original analytical result in many circumstances.

### 3. Procedure

It is essential to make clear who will be comparing results. For example, Australian appointed laboratories have no jurisdiction to correspond with laboratories of exporting countries on behalf of importers where a dispute arises unless formally invited to do so by the responsible Australian authority. Australia suggests that a change be made to the title of 3.1 Step 1 to clarify this:

- "The results and procedures of the laboratory of the exporting country and its counterpart in the importing country are compared by a third party in the member country responsible for the outcome of analytical results".

### 3.1 Step 1: "The Results and Procedures of the Laboratory of the exporting country and its counterpart in the importing country are compared"

Australia recommends that various dot points under Step 1 be rearranged in an order that provides guidance on a logical process for the assessment task required, as follows:

- the accreditation status of the laboratories and the methods of analysis used (including method specific sampling and preparation procedures);
- the raw data (including spectral data, calculations, chemical standards used are assessed and in order);

- internal quality assurance/control (assessment of control charts, sequence of analysis, blank data, recovery data, uncertainty data);
- results of repeat analysis;
- recent performance in proficiency testing studies.

Australia recommends that the entire paragraph after the dot points in Step 1, commencing "One of these two laboratories recognises…" to "… should be selected" should be deleted.

This is in line with our previous comments, recognition of the validity of test results is the jurisdiction of the agency responsible for enforcement on the basis of analytical results, not the laboratories (although the laboratory may provide guidance to regulatory bodies). Furthermore, it is potentially misleading to speculate on reasons for acceptance of one analytical result over another. Given that Codex recognises single laboratory validation and the criteria approach; we believe it is inappropriate to differentiate the status of analytical results on the basis of full validation methods versus single laboratory validation, without objective assessment of supporting information and/or data as specified in the dot points under Step 1.

Australia suggests that the sentence should read:

- "The validity of the analytical result of one laboratory (agreement on conformity or agreement on non-conformity) over the other is determined. Consequently the dispute is solved without new analysis or sampling."

Australia recommends the deletion of the final sentence in Step 1 “If the laboratories cannot find agreement, they may follow the next phase (if samples are available)” and replace it with “If the dispute remains unresolved, two alternate options may be explored.”

In line with our earlier suggestions any reference to agreement between *laboratories* should be deleted. If the dispute remains unresolved on the basis of assessments undertaken in Step 1, member countries should be provided with *options* relevant to the unique situation at hand, rather than following a step wise process given that the next step may be redundant in particular situations and the decision may be made to move to Step 3, if appropriate.

**3.2 Step 2: The Laboratories Carry Out New Analyses**

Step 2 defines comparison of performance by the two laboratories using a common sample, unrelated to the consignment under dispute. It is unclear what the purpose of this step is, given that Step 1 would more than likely identify various differences between methods used and the performances of the two laboratories’ methods through information on results of proficiency test studies of the two laboratories. It should be recognised that the costs involved in undertaking analysis on more than one sample in order to obtain a reasonable estimate of bias, could render this approach as excessive and somewhat irrelevant. Furthermore, it is worth recognising that most laboratories would favour their method as the “most appropriate method of analysis” unless serious reservations were raised under Step 1 of the process.

The third dot point under Step 2 has two distinct scenarios for use of new analytical results that should be considered separately. Australia does not support the use of new analytical results obtained through testing a common (yet unrelated) sample for the purposes of discrediting original test results. The use of an approach such as Step 2 should be clearly defined in order to achieve one desired outcome. Australia believes the desired outcome should be restricted to comparison of performance by the two laboratories and as such the first scenario of the third dot point should be deleted. Australia recommends that the third dot point could simply read:

- “The use of new analytical results: the new results are used to confirm the performance of the importing and/or exporting country’s laboratory.

Under “Operations to be Followed” Australia is concerned with the practicality of the suggestions for “the presence of a laboratory representative of the other laboratory” as part of an alternate option and would suggest that the presence of a representative should not preclude retests to be undertaken in only one laboratory, where appropriate.

**3.3 Step 3: Either A or B**

Step 3 defines scenarios under which a new test result is sought using either reserve samples (A) or entirely new samples taken for the same lot (B). The reason for the importing country to seek a third analytical result should be made clear. That is, importing countries are unlikely to agree to this step if they are convinced of the veracity of the original result after assessment of the laboratory’s performance etc (outlined in Step 1 and 2), however this may not have led to resolution of the dispute.

Australia suggests that the reserve sample must be the same as that tested originally i.e. the remaining analytical sample retained by the laboratory. It should also be recognised that member countries have clearly established policies which may preclude the retest of reserve samples or new samples. For example, in Australia, when an analytical test result provides a positive result in the case of microbiological analyses a third analytical result will not be an option to settle the dispute. Some agreed caveats which define the limitations of the approach in Step 3 for both reserve samples and new samples should be investigated by the CCMAS working group and clearly specified in the document.

**EUROPEAN COMMUNITY**

The European Community and its Member States would like to submit the following comments:

1. The basic procedure should be clear. If the reproducibility limit is used as a criterion for compatibility of results, countries must agree on the reproducibility limit to be applied. Aspects to be dealt with are the assessment of this limit from the measurement uncertainty reported by the disputing labs. It should be noted that in general the dispute is on different samples of the same lot and, therefore, differences can be expected not only from analytical interlaboratory variability, but also from sample differences. If countries agree on an estimating sampling uncertainty, a wider range than the reproducibility limit can be accepted to take the mean of the two results.
2. Different methods may be used according to the draft. In this case the reproducibility limit should be assessed from proficiency studies, as in these studies labs are free to choose their methods. The procedure to be applied in this situation has therefore to be described in detail.
3. The procedure of section 3.2 does not take all practical requirements into consideration. The decision on compliance should be taken within a reasonable period of time i.e., when the results of the final laboratory acting in the frame-work of the dispute-settling procedure are available. Although it is possible to analyse other samples than the dispute samples in this section, the analysis of preferably each of the original samples is preferred, as it might show whether the differences stems from the sample or from the analytical procedures.
4. The analysis of a new sample should be envisaged in exceptional cases only (examples: samples are damaged or stored at too high temperatures, because of a break-down of temperature control).

## PROPOSED DRAFT GUIDELINES FOR SETTLING DISPUTES OVER ANALYTICAL (TEST) RESULTS (AT STEP 3 OF THE PROCEDURE)

### 1. SCOPE:

*These guidelines provide guidance to governments on the procedures to resolve disputes which arise about the status of a product , when the test results by the laboratory [1] in the importing country differ from test results by the laboratory in the exporting country over the same product lot.*

The basic assumption is that the result found by the laboratory in the exporting country was in conformity with the requirements of the importing country.

These guidelines only address disputes related to methods of analysisor laboratory performance or the interpretation of test results [2] and do not address questions of sampling . It is recognized that disputes may arise from other cause(s), which should also be investigated [3].

[1] For the purpose of these guidelines, the word "laboratory" applies to both official and officially recognised laboratories. An official laboratory would be a laboratory administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both. An officially recognised laboratory would be a laboratory that has been formally approved or recognised by a government agency having jurisdiction.

[2] Note that it seems quite unlikely that both laboratories will get exactly the same results, most methods have non-zero repeatability values, which means that any laboratory will get a different result for another test on the same sample, tested at the same time, under the same conditions.

[3] Possible reasons for disagreement may include one or several causes: Differences in sample composition of the samples tested due to product inhomogeneity or due to changes occurring during the storage and transport of the product; Differences in the method of analysis or the laboratory performance; Differences in the specification or results; Differences in the expression of results (corrected for recovery, etc.)

**2. DEFINITIONS :**

| | |
|---|---|
| laboratory A: | laboratory of the exporting country |
| laboratory B: | laboratory of the importing country |
| laboratory C: | third laboratory agreed on by laboratory A and laboratory B |
| sample A1: | original sample analysed by laboratory A |
| sample A2: | reserve sample (preferably by splitting sample A1) stored by laboratory A |
| sample B1: | original sample analysed by Lab B |
| sample B2: | reserve sample (preferably by splitting sample B1) stored by laboratory B |
| sample C: | third sample from the lot concerned, taken in agreement |
| sample D: | sample with a known content |

**3. PREREQUISITES:**

In order to prevent a dispute, before it arises, the following requirements should be stressed:

• laboratories should comply with quality assurance provisions and with the *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and the Export of Food (CAC-GL 27-1997)*; and

• one representative analytical sample from the same product lot (sample A1 and sample B1) should be taken in accordance with established sampling plans, where applicable, and/or good sampling practices; the sample should be split (sample A1 and A2, and sample B1 and B2, respectively) for the purposes of analysis and for confirmatory analysis; the sample should be kept in satisfactory condition for the appropriate length of time (shelf life of the product or at least the time necessary for carrying out commercial transactions).

**4. PROCEDURE:**

The settlement of the dispute without new analysis or sampling operations should be the preferred option as far as possible.

**4.1. – STEP 1: THE RESULTS AND PROCEDURES OF THE LABORATORY OF THE EXPORTING COUNTRY AND ITS COUNTERPART IN THE IMPORTING COUNTRY ARE COMPARED**

When the results on sample A1 and on sample B1 are matching (the ranges indicated by the results and their uncertainties[4] do overlap), the range of overlap should be used to assess conformity.

When the results do not match in the above sense or there is no agreement on the assessment of measurement uncertainty, the comparison concerns:

- the accreditation status of the laboratories and their methods of analysis used;
- the raw data (calculations, standards are in order);
- internal quality assurance/control (recovery, uncertainty, sequence of analysis, control chart, blanks);
- recent performance in proficiency testing studies;
- results of repeat analysis.

One of these two laboratories recognizes the validity of the results of the other laboratory (agreement on conformity or agreement on non conformity) because, for instance :

- one uses a fully validated method and the other uses a methods validated in a single laboratory; or
- each laboratory uses a method validated in a single laboratory and they agree on which of these methods should be selected.

Consequently the dispute is solved without new analysis or sampling.

If the laboratories cannot find an agreement, they may follow the next phase (if samples are available).

**4.2. – STEP 2: THE LABORATORIES CARRY OUT NEW ANALYSES**

**Prerequisites**

Both laboratories agree on:

[4] Based on a confidence level of p=0.95; in case of reported measurement uncertainties being lower than 2 times the reproducibility standard deviation of endorsed methodology, agreement of the laboratories on the procedures used to assess measurement uncertainty is required.

• the exchange/sharing of the samples (A2 and B2), and

• the use of the new analytical results: either the initial results are discarded and the settlement of the dispute only relies on the comparison of the new results obtained; or the new results are used to confirm the validity of one of the two results obtained initially.

A. At this stage, the two laboratories may exchange the reserve samples. Sample B2 is examined by laboratory A and sample A2 is examined by laboratory B.

   If both laboratories confirm the original results received by the other one, obviously, the lot was not homogenous and the constitution of samples A and B differed significantly. In this case 4.3.B. could be followed.

   If both laboratories find the same results in the reserve samples they had before, a major bias in one or both laboratories is obvious.

   In this case the parties may proceed to step 2B or step 3A.

B. The two laboratories may agree to compare performance by testing sample D, a sample with a known analyte content, preferably certified reference material to check for laboratory bias [5].

   The results of the first examination of sample A1 and B1 are then corrected according to the bias found.

   If the results are in agreement the dispute is settled.

If the laboratories cannot come to an agreement, they may choose from the options under 4.3.

**4.3 – STEP 3: EITHER A OR B:**

**A.– Reserve samples (samples A2 and B2) are tested by a third laboratory**

A third laboratory is selected by consensus of the parties or the legal authority of the importing country.

• If the results of the third laboratory samples are in agreement with the results of one of the two laboratories, then the analytical dispute is settled

• Otherwise, the result of the third laboratory on the sample collected by the importing country (sample B2) would be used for determining conformity with the requirements of the importing country:

**B.– New samples (samples C1,C2,C3) taken from the lot are analysed**

In this phase, the initial test results are no longer taken into account.

The modalities of sampling are decided by consensus. According to the wish of the parties, the following

may be carried out :

• representative sampling of the lot is carried out to provide three identical samples (samples C1, C2, C3). One sample (sample C1 and sample C2) is forwarded to each of the laboratories for analysis.

- the results obtained are in agreement: the analytical dispute is settled.
- the results are not in agreement: the third sample (sample C3) is sent to a third laboratory that has been selected by consensus by the parties or the legal authority of the importing country. Its results are used as reference: the analytical dispute is settled.

• representative sampling of the lot is carried out to provide one single sample (sample C). It is sent to one of the laboratories that performs the analysis in the presence of a representative of the second laboratory.

The results are used as reference: the analytical dispute is settled.

[5] To investigate analytical differences (biases) between laboratories, the laboratories need to test samples whose analyte concentrations are known (usually duplicate split samples). It is not necessary to test or retest samples from the original lot of product under dispute: this would only be required if a reassessment of the lot were needed. To provide a reasonable estimate of bias, several (split) samples should be analysed, one duplicate of each sample at each laboratory. The appropriate number of samples should be used for the estimate of the bias to be reliable.

**JAPAN**

3.1 - STEP 1, the first paragraph

As CCMAS agreed at its 24th session, this document deals with two situations: 1) the same validated method is used by both laboratories; and 2) different validated methods are used by each laboratory. However, it is not clear whether STEP 1 covers the second case where different methods are used.

When different methods are used with their reproducibility limits being not significantly different, the analyses may be considered to be performed under reproducibility conditions and their reproducibility limits are used for comparison. When different methods are used with their reproducibility limits being significantly different, the analyses are not considered to be performed under reproducibility conditions. The document should clearly mention whether the first paragraph of STEP 1 covers these cases.

In case the first paragraph of STEP 1 covers the latter case too, a text such as follows should be added.

> "When the difference between the two results is within the reproducibility limit of the test method used in an exporting country and that of the test method used in an importing country, the mean of the two results should be used to assess conformity, taking into account measurement uncertainty. When the difference between the two results is not within either of the reproducibility limits, the comparison concerns:"

3.2. - STEP 2

It can be understood that in Step 2 analyses are performed on reserve samples. This should clearly be mentioned in this sub-section. If shared samples are not reserve samples, it should be clear what shared samples indicate.

In addition, "two analyses" in Operations to be followed should be further explained. We would like to propose an addition and an amendment as follows:

1) Addition of the following sentence as the third bullet for Prerequisites.

> **"** the laboratory where the analyses should be performed if one of the laboratories perform analyses; and"

2) Amendment to the first sentence of "Operations to be followed".

> "Each laboratory may perform ~~new~~ analyses on shared **reserve** samples or ~~two analyses may be performed in one laboratory~~ **one of the laboratories may perform analyses on reserve samples** in the presence of a representative of the other laboratory."

**3.3. - STEP 3, A and the second bullet of B**

The method of analysis to be used should be mentioned.

**MALAYSIA**

**1. SCOPE**

Malaysia proposes to add the word *"within a reasonable time frame"* in the paragraph. This paragraph is to read:

*"These guidelines provide guidance to governments on the procedures to resolve disputes which arise about the status of a product[1]* ***within a reasonable time frame****, when the test results by the laboratory[2] in the importing country disagree with test results by the laboratory in the exporting country over the same product lot".*

**2. PREREQUISITES:**

Malaysia noticed a typographical error in the first sentence *"its"*. Malaysia proposes to change the word with *"it"*. The sentence will read as:

***" In order to try prevent a dispute, before it arises, the following requirements should be stressed".***

In the second bullet, Malaysia proposes to:

i) Delete the word *"~~ans/or~~"* and replace with the word ***"and/or".***

**ii)** Delete the word *"~~sampleshould~~"* and replace with the word ***"sample should".***

iii) Delete the words *"~~split~~"* and replace with the word ***"taken".***

The sentence is to read:

- *" one representative analytical sample from the same product lot should be taken in accordance with establish sampling, where applicable, plans **and/or** good sampling practices; the same **sample should** be **taken** for the purposes of analysis and for confirmatory analysis; the sample should be kept in satisfactory conditions for the appropriate length of time (shelf life of the product or at least the time necessary for carrying out commercial transactions)".*

**PROCEDURE**

**2.1 STEP 1: THE RESULTS AND PROCEDURES OF THE LABORATORY OF THE EXPORTING COUNTRY AND ITS COUNTERPART IN THE IMPORTING COUNTRY ARE COMPARED**

We noticed a typographical error in the word:

i) *"reproductbility"* in the first line and *"reproductibility"* in the second line. The word should be *"reproducibility"*.

The sentence will read as:

*"When the results are within the **reproducibility** limit the mean should be used to assess conformity, taking into account measurement uncertainty. When results are outside the **reproducibility** limit, the comparison concerns".*

ii) *"laboratoiries"* in the first bullet. The word should be *"laboratories"*.

The sentence will read as:

- *"the accreditation status of the **laboratories** and their methods of analysis used".*

iii) *"methods"* in the sixth bullet. The word should be *"method"*.

The sentence will read as:

- *"one uses a fully validated method and the other uses a **method** validated in a single laboratory; or".*

**3.3– STEP 3: EITHER A OR B:**

Malaysia proposes to add the word :

i)*" or new samples (whichever applicable)"* in Step 3A. The sentence will read as:

***"A. – reserve samples or new samples (whichever is applicable) are tested by a third laboratory".***

ii) "*which should comply with CAC-GL 27-1997 as in Prerequisites"* in the second sentence. The sentence will read as:

*"A third laboratory **which should comply with CAC-GL 27-1997 as in Prerequisites** is selected by consensus of the parties or the legal authority of the importing country".*

iii) *"the third laboratory shall use a method of analysis jointly agreed by both importing and exporting countries"* as a first bullet. The sentence will read as:

*"A third laboratory is selected by consensus of the parties or the legal authority of the importing country.*

- ***The third laboratory shall use a method of analysis jointly agreed by both importing and exporting countries".***

**NEW ZEALAND**

**GENERAL COMMENTS**

This draft represents a considerable improvement on previous versions, but we still have some concerns about it as outlined below.

**Context of the Guidelines**

To treat the matter as a "dispute" may not give quite the right flavour to the procedure. It seems more a matter of *resolving a difference in results* to a point where there is agreement on a "most plausible" set of results.

**Other causes of disputes**

Some guidance should be available to enable users to rule out disputes arising from other causes, that is, sampling issues and the interpretation of test results as indicated in footnote 4. This is a necessary first step before proceeding to address analytical testing differences between the laboratories as the cause of the dispute; otherwise inappropriate measures might be used to resolve the dispute.

Some guidance is also needed on how to eliminate issues not related to testing. It is suggested that as a starting point, the two laboratories could compare how their samples were taken and how their decisions on conformity was made.

**Development of Detail**

We suggest that the guidelines should be separated into two parts: a general overview of the dispute resolution process, and a technical appendix providing detailed guidance.

In the general overview, comparisons of product assessments should be left at the more subjective level, and the technical appendix could describe how these comparisons are actually made. We consider such detailed information is essential for avoidance of disputes.

References to the use of the reproducibility as a benchmark for comparing results from two laboratories should be removed, and placed in the proposed appendix. However reproducibility may not in fact be appropriate as it applies only to the comparison of single test results, and this comparison is a poor test for bias. One should compare the conformity assessments, which may be based on more than one test result and may include some tolerances. However the comparison of unknown samples leaves unresolved the issue of which laboratory has produced the more correct results.

**Sequence of Steps**

There will usually be a number of possible causes of disputes, some of which would be easier to investigate than others, and there seems no reason why these should be investigated sequentially. The two laboratories should be free to negotiate a settlement in any way they see appropriate.

Nevertheless the use of a third laboratory to arbitrate should be seen only as a last resort. If adopted as a routine measure this could, at worst, have the effect of placing the ownership of all future product assessments into the hands of a third laboratory. It should be indicated as an option that may be taken by the two laboratories to resolve a dispute, but should not be included in a general procedure.

**Product Assessment**

The guidelines seem to assume that both the exporter and the importer rely on single results for assessments of product, possibly allowing only for measurement uncertainty. Generally this might not be the case. Multiple sample assessments are possible and might involve consideration of sampling as well as measurement errors.

**SPECIFIC COMMENTS**

**1 Scope**

**Footnote 1**

This note refers to “result” but needs to be more general to cover “assessments”, possibly made using several results. (There is a difference between results and assessments made using those results).

**Footnote 3**

Reproducibility is the relevant concept when comparing two results, one from each laboratory. However it is possible that the two laboratories may not be using exactly the same method, which is not included in the standard definition. One would therefore need a 'generalised reproducibility', derived from the reproducibilities of the two methods, taking account of the performance of the two methods.

## 2 Prerequisites

The second condition, that a sample be retained, is more to facilitate the resolution of disputes, should they occur, rather than to prevent disputes arising.

We question the need to retain samples as recommended, because it could lead to producers and exporters holding large inventories of samples, just in case of disputes. If there is a dispute concerning product acceptability, then some of that product will still exist and be available for sampling if needed.

It is not clear what is expected in the case of inhomogeneous products, whether producers or exporters are expected to retain several samples from each production lot, and if so how many. This would further increase the cost of retention of samples.

## 3 Procedure

If differences between laboratories' performances are being investigated, it seems that the most important thing is to get both laboratories to analyse duplicate samples of the same material (and not just material drawn from the same lot), preferably in conjunction with material of known or accepted analyte levels (reference samples). Ideally duplicates of the material on which a finding of non-conformity was based should be sent to the other laboratory for analysis. The value of reference material to be analysed in conjunction with these duplicates must be emphasised. We note that there is no reference to this in the procedure. Granted, reference material at an appropriate analyte level will not always be available, but if it is, it has the potential to lead to an easy settlement of the dispute.

**Step 1**

At this stage it is quite likely that the producer and importing country will not have tested exactly the same sample, so there may be some need to allow for variation within the lot of product and a criterion based on reproducibility alone may not be appropriate.

The use of an "average" set of results on a routine basis is generous to the exporter. It essentially gives him two opportunities to pass the compliance test, provided only that he raises a dispute.

As suggested above, this sort of material should be placed in a technical appendix.

A list of considerations is given but it is not clear how a decision should be reached as to which laboratory has the more correct assessment or whether this is a matter of negotiation.

A laboratory that uses a fully validated method does not necessarily have superior performance to a laboratory using a method validated in only a single laboratory. Certainly the former laboratory may have greater credibility from using the fully validated method but the latter laboratory probably has good reason for using the method it uses.

**Step 2**

There is no mention of how the results are to be compared to decide which laboratory has produced the more correct results.

The sharing of unknown samples does not resolve the issue of which laboratory is producing results closer to the correct values, since there is no reference to the true values.

Again we suggest that this material should be dealt with in a technical appendix.

**Step 3A**

**Use of a Third Laboratory**

This could be an option taken by the two laboratories to resolve a dispute, but should not be included in a general procedure.

**Step 3B**

Testing issues, particularly bias, can only be resolved by testing duplicates of the same sample, one at each laboratory, otherwise there will inevitably be differences in composition due to variability of the parameter within the product.

The producer may not have retained sufficient samples to provide much flexibility in the way samples are selected for retesting.

The procedure needs to be broadened to take account of assessments based on multiple samples taken from a lot.

'Agreement' is not defined objectively.