codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3b) **CX/MAS 06/27/4-Add.1**

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 (At Step 3 of the Elaboration Procedure)[1]

REVISED VERSION

(Prepared by a drafting group led by France)

BACKGROUND

1. The 26th Session of the Committee on Methods of Analysis and Sampling discussed the Proposed Draft Guidelines for Settling Disputes over Analytical (Test) Results, and agreed on a number of amendments to the text of the Proposed Draft presented in document CX/MAS 05/27/5. A revised version was further discussed during the session as CRD 18. The Committee concluded that, despite significant progress made on the revision of the document, there was still a need to discuss it in more detail, however due to time constraints it was not feasible to do so at the current session.
2. The Committee agreed that the Proposed Draft Guidelines would be circulated at Step 3 in a separate Circular Letter, by the end of May 2005, after editorial review by the Delegation of France. The comments would be directed to the Delegation of France who would revise the document with assistance of an electronic Working Group, for further comments if time allowed, and consideration at the next session (ALINORM 05/28/23, paras. 27-42).
3. The Proposed Draft Guidelines, as redrafted by the Delegation of France, have been circulated for comments before the 1st September 2005, as Codex circular letter CL 2005/28-MAS (May 2005). The delegations of Argentina, Australia, European Community and Japan have responded to this circular letter.
4. Taking into account these comments, the delegation of France has revised the text again and sought comments on this new draft from the members of an electronic drafting group[2], as agreed by the 26th session of CCMAS. The delegations of Argentina, Australia, European Commission, Japan, Norway, New Zealand and Thailand have responded during this second round of comments.
5. The French delegation has further revised the draft in order to prepare the final version of the Proposed Draft Guidelines that will be considered by the 27th Session of the Committee, taking into account the comments received.

OUTLINE OF THE PROCEDURE:

6. The complexities of real dispute situations and the inadequacy and paucity of the information available to settle a dispute expeditiously are obvious. On the other hand, the usefulness of any procedure

[1] Comments at Step 3 in reply to CL 2005/28-MAS are included in CX/MAS 06/27/4

[2] Argentina, Australia, Austria, Belgium, Brazil, Canada, European Community, Finland, Germany, Japan, Netherlands, New-Zealand, Norway, Poland, South Africa, Sweden, Switzerland, United Kingdom, United States, AOCS, IDF

applicable in such situations is a matter of balance between the constraints it imposes on the trade and the efficiency and speed with which an acceptable solution is found between the two contending competent authorities. It seems, to some extent, that the accuracy of the outcome, as gauged on analytical and statistical grounds, may not be the sole consideration. The owner of the consignment would also consider the extra costs incurred in fulfilling the prerequisites needed to use the procedure in case of need (laboratory and sampling costs, for instance), the possible losses induced by impediment or delays in trade flow, the nature and value of food consignment, the history of non-conformity for the type of food in international trade. It is indeed a matter for businesses to decide on the basis of cost management and profitability of trade.

7. The approach suggested in these draft Guidelines takes into account, as far as possible, the practical constraints on traders and competent authorities, responsible for the control of foodstuffs in international trade.

8. The proposed Guidelines do not address any dispute situation. Both competent authorities should have assessed conformity of a food consignment on the basis of laboratory test results and these assessments should differ. The settlement of the dispute without new analysis or sampling operations should be the preferred option, as far as possible.

9. At the outset, the Guidelines clearly state prerequisites for successful use of the procedure and also the situations it could not address properly.

10. At step 1, the available information is minimal: the priority, at this stage, is to screen out as many apparent dispute situations as possible, applying a simple criterion and making full use of the limited information available. Only when the dispute is not resolved so easily, the context for the initial information is investigated (step 2 of the procedure). This section of the Guidelines lists the relevant information to be exchanged to enable a new assessment by the two competent authorities to successfully bring an end to the dispute.

11. If the lack of resolution of the dispute makes resort to new analysis and/or sampling operations inevitable, the Guidelines (Steps 3 and 4) clearly specify the prerequisites to be implemented before new analysis (Step 3: reserve sample) or ultimately new sampling operations (Step 4) be performed in a coordinated manner.

MAIN ISSUES IN THE WRITTEN COMMENTS

GENERAL COMMENTS:

12. It is not appropriate to consider cases that do not produce disagreement between competent authorities, for instance, as described in one comment, when "two laboratories have the same result which may in fact not be the true value." It is indeed unfortunate that the two competent authorities make independently a wrong judgement, on the basis of the information available to each. But, for the purpose of these Guidelines, it is not appropriate to make additional assumption on the accuracy of at least one test result.

13. The terminology has been modified: "product" or "lot" have been replaced by "food consignment", as one delegation has pointed out that, in practice, a single consignment could be divided in several "lots".

14. 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 to undertake steps towards dispute resolution over analytical (test) results, some concern was expressed that the draft Guideline could create confusion regarding the role of the laboratory, as the responsible body for settling disputes over analytical (test) results, has been taken care of by amending the initial text extensively. To this effect, the phrase "competent authority" has been retained, as it is standard in CCFICS texts.

15. Clarification has been provided, in the new draft, on the requirement for retest on “common” and “reserve” samples, as it was pointed out that, unless laboratories are retesting identical samples it is unlikely that disputes over analytical test results will be resolved effectively. The text explains how reserve samples are obtained and how they are used during the relevant steps of the procedure.

COMMENTS ON SPECIFIC STEPS

16. A practical criterion for determining conformity, using the reproducibility limit has been established. Different types of situations have been addressed in the current version: both laboratories have used the same methods or not; reproducibility limits have been published for that method or not. Furthermore, laboratories would work with in-house validated methods with non published reproducibilities as is often the case for contaminants, pesticides, heavy metals or xenobiotics. The proposed criterion may be implemented flexibly in all these situations.

17. The ANNEX suggests a simple procedure, based on the Horwitz's model, to apply this criterion and resolve the dispute. When available or recognised other models than Horwitz's could be used. The procedure is independent of method(s) of analysis used. As suggested by one comment, a variant has been included to address different concentration ranges .(step 1 – § 3.1)

18. The list of information to be shared by food control authorities, to compare performance of the laboratories involved has been amended and its items reordered following suggestions made in some of the comments received. (Step 2 – § 3.2). The last part of this section has been completely redrafted as no simple decision rule could be established based on the comments received from members of the electronic drafting group and as it appears that nothing, short of a full reconsideration of the initial assessments using more complete information, was adequate.

19. The last two sections have been completely redrafted in order to clarify the prerequisite required before seeking the resolution of the dispute by carrying out new analyses of "reserve" samples and the possible three approaches and their expected outcomes at this stage in the process. (Step 3 – § 3.3). Among the three suggested approaches, one approach helps identify that test results are not responsible for the dispute.

20. The last step involves a new sampling operation followed by new analyses. During the last session of the CCMAS, some delegations pointed out that the last section exceeded the scope of these Draft Guidelines, as it did not provide a means to resolve the current dispute over analytical results but simply advised to start the process all over again, generating new, possibly incompatible, analytical results. This section was redrafted to emphasise that conditions under which is new sampling and analyses are carried out are different from the initial situation leading to the dispute and it provides a simple process to initiate this last step.

RECOMMENDATION TO THE COMMITTEE:

21. After considering the revised draft Guidelines at its 27th session, the Committee wish to forward this text to the next session of the Codex alimentarius Commission for adoption at step 5/8.

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

1. SCOPE:

These guidelines provide guidance to governments on the procedures to resolve disputes which arise between food control authorities about the status of a food consignment[3]*, when the test results by the laboratory*[4] *in the importing country disagree with test results by the laboratory in the exporting country over the same consignment.*

The basic assumption is that the results 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 analysis or laboratory performance and do not address questions of sampling and/or of interpretation of test results[5]. It is recognised that disputes may arise from other cause(s), which should also be investigated. Guidance on issues related to measurement uncertainty is provided by *International Laboratory Accreditation Cooperation, annex A (ILAC-G8/1996)*.

2. PREREQUISITES:

The procedure described in these Guidelines may only be used when:

- laboratories comply with quality assurance provisions and with the Codex *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and the Export of Food (CAC-GL 27)*; and
- one representative analytical laboratory sample from the same food consignment should be taken in accordance with established sampling plans and/or good sampling practices, where applicable; the laboratory sample should be split for the purposes of analysis and for confirmatory analysis (reserve sample); the reserve sample should be kept in a satisfactory condition for the appropriate length of time.

3. PROCEDURE:

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

3.1. – STEP 1: THE ANALYTICAL RESULTS ARE COMPARED USING THE REPRODUCIBILITY LIMIT

When the results are within the reproducibility limit the mean value should be used to assess conformity, taking into account measurement uncertainty.

When both laboratories have used the same method of analysis, and when published reproducibility limits exist for the method, these limits should be used.

In all other cases, the ANNEX suggests a simple procedure, based on the Horwitz's model, to implement this criterion and resolve the dispute. When available or recognised, other models than Horwitz's could be used.

If results are outside the reproducibility limit, the attempt to resolve the dispute should proceed to step 2.

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[3] Status of the food consignment depends on the "interpretation" of the test result(s), in the light of measurement uncertainty, sampling error and the closeness of those test results to the limit. It could still be that the results do not differ by an amount which is significant, but nevertheless one result indicates conformity, but the other result does not.

[4] 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.

[5] Possible reasons for disagreement may include one or several causes such as : differences in composition of the samples tested due to inhomogeneity or changes occurring during storage and/or transport; differences in the methods of analysis or the laboratory performance; differences in the specification or results; differences in the expression of results (corrected for recovery, etc),...

3.2. – STEP 2: THE RESULTS AND PROCEDURES OF THE LABORATORY OF THE EXPORTING COUNTRY AND ITS COUNTERPART IN THE IMPORTING COUNTRY ARE COMPARED

In accordance with relevant Codex Guidelines[6], the following information should be shared between competent authorities of the importing and exporting country to allow comparison of the results and procedures of the laboratory of the exporting country and its counterpart in the importing country. The relevant information covers:

- accreditation status of the laboratories and validation status of the methods of analysis used (including method specific sampling and preparation procedures),
- raw data (including spectral data, calculations, chemical standards used are assessed and are in order),
- external (track record in proficiency and performance) and/or internal quality assurance/control (assessment of control charts, sequence of analysis, blank data, recovery data, uncertainty data, use of appropriate reference standards and materials),
- results of repeat analysis,
- results of confirmatory analysis,
- performance in relevant proficiency testing or collaborative studies.

Each competent authority reviews its initial assessment on the basis of the additional information received from the other in order to recognise the validity of the results of one of the two laboratories is recognised (agreement on conformity or agreement on non conformity).
In this way, the dispute is resolved without further analysis or sampling.
If no agreement is reached, resolution of the dispute may be sought using the next step (where reserve samples are available).

3.3. – STEP 3: NEW ANALYSES ARE CARRIED OUT

Prerequisites
There is an agreement on:

- the sharing/swapping of the reserve samples,
- the methods of analysis,
- the laboratories involved: each laboratory may undertake new analyses or one laboratory in the presence of a representative of the other; or a third laboratory may be selected by consensus, or, failing that, by the food control authority of the importing country; and
- the use of the new analytical results: either the initial results are discarded and the settlement of the dispute is determined by 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.

Available approaches
One (or more) may be selected.
A.– SEARCH FOR LABORATORY BIAS
It may be agreed to check for laboratory bias, by testing common samples.[7] Performances are compared by testing a common sample with a known analyte content, preferably certified reference material. The original results are then corrected according to the bias found. If the results are in agreement, within the reproducibility limit, the dispute is settled.
B.– IDENTIFICATION OF A SAMPLING PROBLEM

[6] See ANNEX to GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD (CAC/GL 25-1997) : "Where imported food has been rejected on the basis of sampling and/or analysis in the importing country, details should be made available on request as to sampling and analytical methods and test results and the identity of the testing laboratory."

[7] To investigate analytical differences (biases) between laboratories, the laboratories need to test samples with known analyte concentrations (usually duplicate split samples). It is not necessary to test or retest samples from the original food consignment under dispute. 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.

The two laboratories may swap their reserve samples. If both laboratories confirm the original results received by the other one, a sampling problem is identified.

C.– ANALYSES OF RESERVE SAMPLES

The new analyses are performed on shared reserve samples. Either:

- analyses are performed in one laboratory in the presence of a representative of the other laboratory. The new results are used to assess conformity.
- the two laboratories carry analyses separately: If the new results are in agreement, the dispute is settled. If no agreement is reached, resolution of the dispute may be sought by proceeding to step 4.

3.4 – STEP 4: New samples taken from the consignment are analysed

The consignment is located in the importing country. At this stage, the initial test results are no longer taken into account. The modalities of sampling and analysis are decided by consensus.

At the request of the food control authority of the exporting country, a new sampling of the consignment is carried out and new analyses are performed in a laboratory selected by consensus or, failing that, by the food control authority of the importing country.

ANNEX

Definition of a maximum acceptable difference Δ_{max}

Let define the average contents of the sample T and the relative difference between results $\Delta\%$ as:

$$T = \frac{Y_1 + Y_2}{2}$$

$$\Delta\% = \frac{|Y_1 - Y_2|}{T} \times 100$$

The acceptation condition is that the difference between both results is below reproducibility limit defined in ISO 5725 from the reproducibility standard deviation s_R:

$$|Y_1 - Y_2| \leq 2.83 s_R$$

If there is no published reproducibility, it is possible to use the model of Horwitz to calculate the limit of reproducibility as:

$$s_R = 0.02 \times T^{0.8495}$$

Then it comes:

$$|Y_1 - Y_2| \leq 0.0566 \times T^{0.8495}$$

Thus, the maximal acceptable difference (relative) is:

$$\Delta_{max} \leq \frac{0.0566 \times T^{0.8495}}{T} \times 100$$

Figure 1 illustrates, as an abacus, this decision criterion. When dealing with concentration around 1 ppm, the relative difference between results must be below 45%. This value seems rather high but, for instance, it is often consistent with the toxicological meaning of a contaminant. When available or recognized other models than Horwitz's could be used (see Table 1).

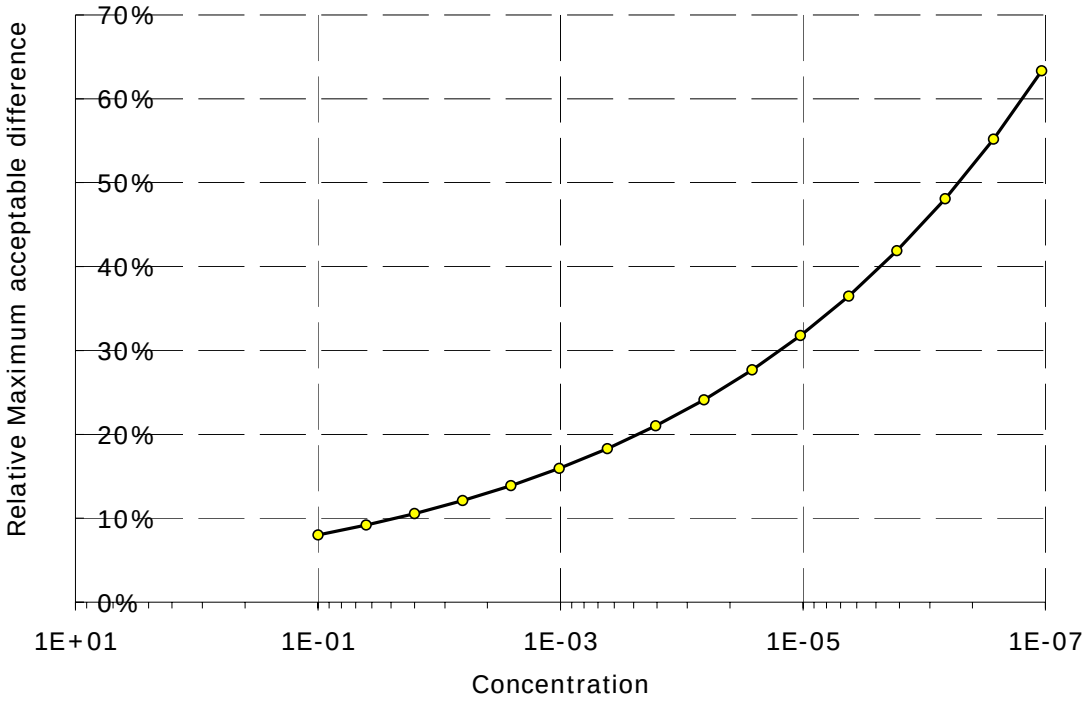

Figure 1. Relative Maximum acceptable difference based on Horwitz's model

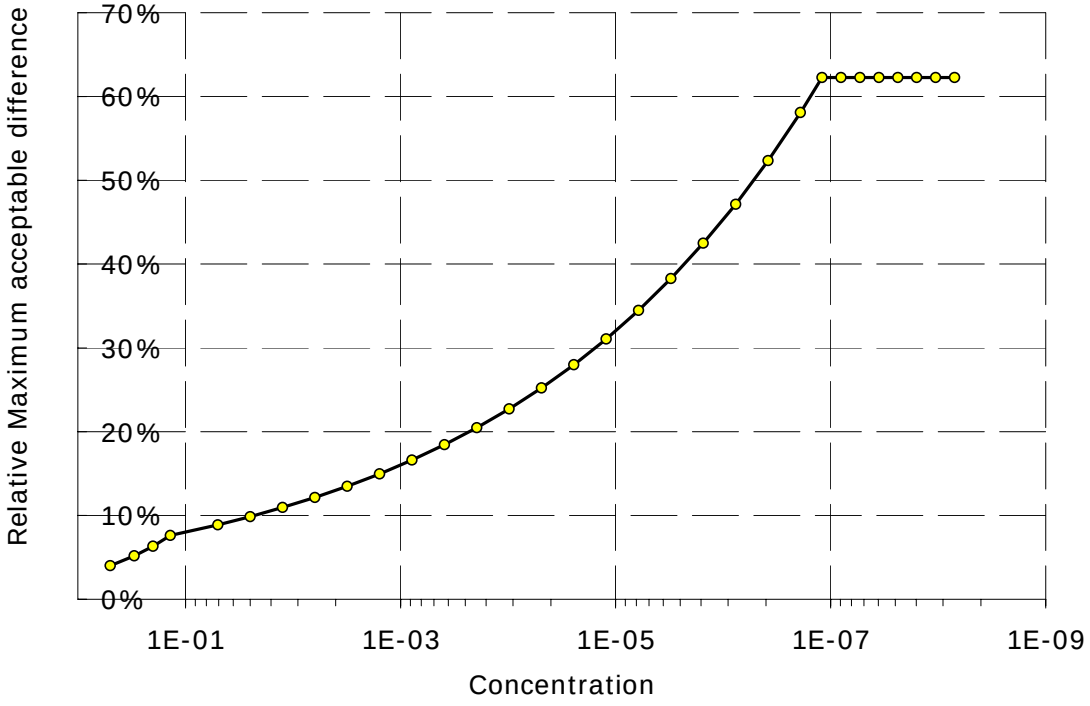

Figure 2. Relative Maximum acceptable difference based on Thompson's model

Table 1. Published recognized models

Name	Range (dimensionless)	Equation of s_R	Equation for Δ_{max} (%)	Figure
Horwitz [1]	10^{-1} to 10^{-7}	$s_R = 0.02 \times T^{0.8495}$	$\Delta_{max} \leq \frac{5.66 \times T^{0.8495}}{T}$	2
Thompson [2]	≥ 0.138	$s_R = 0.01 \times T^{0.5}$	$\Delta_{max} \leq \frac{2.83 \times T^{0.5}}{T}$	3
	0.138 to 1.2 × 10^{-7}	$s_R = 0.02 \times T^{0.8495}$	$\Delta_{max} \leq \frac{5.66 \times T^{0.8495}}{T}$	
	$\leq 1.2 \times 10^{-7}$	$s_R = 0.22 \times T$	62.26%	

References

[1] Horwitz W. (1980) Quality Assurance in the Analysis of Foods for Trace Constituents, *J of the AOAC* 63:6, 1344-1354

[2] Thompson M. (2000) Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing, *Analyst* 125, 385-386