codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3 c) **CX/MAS 05/26/5**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Twenty-sixth Session
Budapest, Hungary, 4 – 8 April 2005

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

The Proposed Draft Guidelines are distributed for comments at Step 3. Governments and international organizations wishing to comment are invited to do so in writing, preferably by Email, to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, Fax: +39 (06) 5705 4593, e-mail : codex@fao.org with a copy to Dr. Mária Váradi, Central Food Research Institute (KÉKI), H-1022 Budapest, Herman Ottó út 15 (Fax No., +361.212.9853 & 361.355.8928; e-mail, m.varadi@cfri.hu **before 25 March 2005**.

INTRODUCTION

1. This question was raised for the first time at the 21st Session of the CCMAS.

2. France proposed a first draft under reference CX/MAS 98/5 Annex 4, that was also considered by the CCFICS. The work was referred back to the CCMAS and a second proposal under reference CX/MAS 02/04-Add.2 was considered by the 24th Session. A Conference Room Document (CRD 17) was drafted. This question was on the Agenda of the 25th Session although no new document had been proposed. This question was discussed and the French rapporteur and the drafting group were requested to prepare a draft on the basis of the proposals made in 1998. The drafting group should address only the disputes related to analytical methodology and should not consider sampling issues.

3. The issue of disputes was actually introduced during the 24th Session and its importance is recalled in various sections of the report (ALINORM 03/23).

4. This question was considered first as regards the use of analytical results (paras. 110-117):

"The Delegation of the United Kingdom introduced the document and indicated that decisions regarding the acceptability of a lot or sample should be based on a concept that takes sampling and analytical aspects into consideration. The Delegation pointed out that at the present time there was no common understanding and interpretation of analytical results among Codex Members and therefore different decisions might be taken after an analysis of the same sample. The Delegation indicated that it occurred because some countries took into account uncertainty for the interpretation of results while others did not and that different sampling regimes were used. The Delegation indicated that approaches to solve these problems were presented in the annexes of the document. The Delegation proposed that when Commodity Committees develop specifications they should do it with respect to those factors which affect the interpretation of specifications. Therefore Commodity Committees should give clear guidance to the Committee on Methods of Analysis and Sampling on how they wished Codex specifications to be enforced.

Many delegations emphasized the importance of this issue in order to ensure consistency throughout Codex and supported efforts in this field.

The Observer from the EC pointed out that this matter was of major importance as issues related to the correction for measurement uncertainty, recovery and sampling uncertainty had consequences which could not be ignored. The Observer informed the Committee about the ongoing work in the EC and indicated that a draft document in this area was available for information.

The Delegation of Germany indicated that from the scientific point of view there was a need to take into account uncertainty and that was consistent with the requirement to prove "beyond reasonable doubt" that a limit had been exceeded. The Delegation pointed out that there should be a mechanism to ensure that commodities were dealt with consistently and proposed to work on general recommendations for Commodity Committees.

The Delegation of the Netherlands drew the attention of the Committee to the fact that in the area of pesticide residues there was no correction for recovery while in other areas correction was applied and it was not clear enough to whom recommendations could be addressed. The Delegation therefore suggested to make relevant changes in the Procedural Manual so as to ensure that Commodity Committees applied a consistent approach on this issue.

The Delegation of Ireland indicated that this matter had been linked with dispute situations related to analytical and sampling errors and suggested to proceed in a step-wise manner by drawing very pragmatic guidelines. The Delegation informed the Committee that the International Laboratory Accreditation Body had established guidelines in this regard which were available from their website (www.ilac.org).

Some delegations were of the view that before proceeding further this problem should be addressed by Commodity Committees as they should consider how the analytical results would be used when developing provisions in Codex Standards.

The Committee agreed to forward this document containing explanatory notes (CX/MAS 02/12) to Commodity Committees for their consideration and comments. The Committee also agreed to forward this document to the Committee on Food Import and Export Inspection and Certification Systems and ask its advice insofar as inspection issues were involved."

5. Then as regards the elaboration of Codex methods of Analysis (para. 38):

"The Delegation of the United States, while supporting the criteria approach in principle for both Types, expressed the view that Type II methods should not be eliminated before dispute situations had been addressed, and also proposed to include examples to clarify its application."

6. Regarding the consideration of dispute situations (paras. 27 to 32):

"The Committee recalled that its last session had discussed dispute situations in the framework of the criteria approach and had agreed that the Delegation of France, in cooperation with other countries, would prepare a document addressing this question.

The Delegation of France presented a document based on some sections of ISO 4259:2000, and proposing procedures for settling inter-laboratory disputes, in the absence of specific rules set out in the specification or mentioned in the test method. The document provided a step by step approach to identify the causes of disagreement between laboratories on analytical results and facilitate their settlement. On this basis, the Delegation proposed to initiate new work on guidelines for dispute settlement.

Some delegations expressed the view that although the document followed a scientific approach, it was too complex for the purposes of Codex and a simpler and more practical approach should be followed, as proposed in the written comments of Thailand. Reference was also made to the earlier recommendations of the Committee on Food Import and Export Inspection and Certification Systems to the effect that recommendations in this area should not be too prescriptive.

After some discussion, it was agreed that the Delegation of France, in cooperation with the delegations of Australia, Canada, Finland, New Zealand, Netherlands, Sweden, United Kingdom, United States would work during the session to propose a revised outline. The result of these discussions was presented to the Committee in CRD 17 "Proposal for New Work on Dispute Situations".

The Committee welcomed this proposal and recognized that disputes might arise from differences due to sampling; differences in the analytical procedures; and differences in the interpretation of test results. Some delegations supported considering all types of disputes, including the differences relating to sampling plans. However the Committee agreed to concentrate on the settlement of differences in analytical procedures at this stage, and to develop guidelines that would deal with two situations 1) the same validated method is used by both laboratories; 2) two different validated methods are used by each laboratory. The guidelines would specify how this apparent disagreement could be resolved step by step.

The Committee agreed to initiate new work on Proposed Draft Guidelines for Settling Disputes over Analytical (Test) Results, to be developed by the Delegation of France in cooperation with a Drafting Group for consideration by the next session, subject to the approval of the Commission".

7. And as a last reference (ALINORM 04/27/23, paras. 55 to 58):

"The Committee recalled that its last session had agreed that the delegation of France would develop Proposed Draft Guidelines to address disputes arising from differences in laboratory results, and that this new work had subsequently been approved by the Commission.

The Delegation of France informed the Committee that it had not been able to prepare the document as several related issues were still under discussion in the Committee and had not yet been resolved, such as sampling, measurement uncertainty and the use of recovery factors, the use of significant figures, the application of specifications to the lot or the unit. The Delegation recalled that it had prepared a document at the last session based on ISO 4529:2000 including a procedure for the declaration of conformity and that it had been considered too complex for practical use, but that guidelines in this area should follow a scientific approach.

Several delegations supported the development of guidance for governments in order to facilitate dispute settlements and pointed out that the document should be practical enough to be used by governments. The Committee agreed that the document should address only disputes related to analytical methodology and should not consider sampling issues.

The Committee agreed that the Delegation of France would prepare a new version of the Proposed Draft Guidelines for consideration by the next session."

RECOMMENDATION

8. The Committee is invited to consider the text presented in Annex 1 and if it agrees to proceed with this work, to provide guidance to the drafters on the scope to be covered by a document presenting a procedure of dispute settlement for inter-laboratory disputes over analytical results.

ANNEX 1

PROCEDURE FOR SETTLING INTERLABORATORY DISPUTES OVER ANALYTICAL (TEST) RESULTS

Disputes arise when the official laboratory in the importing country does not find the same test results as the official laboratory in the exporting country for the same product lot.

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

This disagreement may originate from one or several causes:

- Differences in the sample composition (keeping condition)
- Difference in the method of analysis or the laboratory performance
- Difference in the interpretation of the specification or results

This document only addresses disputes related to analytical methodology and does not address sampling questions.

Prerequisites

In order to be able to settle a dispute, the following requirements should be stressed:

- laboratories should comply with quality assurance provisions; and
- two samples coming from the same product should be taken: one sample for the purposes of analysis, and another for confirmatory analysis, that should be kept in satisfactory conditions for the appropriate length of time (shelf life of the product or at least the delay necessary for carrying out commercial transactions).

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

1. The official laboratory of the exporting country and its counterpart in the importing country compare their procedures and results

This comparison concerns the results obtained, the methods of analysis used, the expression of the results, the recovery ratio, measurement uncertainty and all conditions in which the result is obtained that are likely to affect analytical results.

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

- 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 follow the next phase (if samples are available).

2. The laboratories carry out new analyses

Prerequisites

Both laboratories agree on:

- the sharing of the samples, and
- the most appropriate method of analysis; and
- the interpretation to be given to new analytical results: either the initial results are discarded and the settlement of the dispute relies only 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.

Operations to be followed

Each laboratory may perform new analyses on one or the other of the samples kept by the laboratories or two analyses may be performed in one laboratory in the presence of a representative of the second laboratory.

If the laboratories cannot find an agreement, they follow the next phase (if the lot still exists).

3. New samples taken from the lot are analysed

In this phase, the initial analyses 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 on three samples.
  - one sample is forwarded to each of the laboratories for analysis according to the method selected jointly by the laboratories.
  - the results obtained are identical: the analytical dispute is settled.
  - the results are different: the third sample is sent to a third laboratory that has been selected by consensus by the parties or the legal authority of the importing country. This laboratory must use the same method. Its results are used as reference: the analytical dispute is settled.
- representative sampling is carried out on one single sample.

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.

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ANNEX 2

Earlier working documents to be consulted

CCMAS	Report	Working Documents
21st Session 10 - 14/03/1997	ALINORM 97/23 paras. 12 and 14	
22nd Session 23 - 27/11/1998	ALINORM 99/23 paras. 29 to 31	Annexe 4 document 98/5
23rd Session 26/ 02 - 02 03 2001	ALINORM 01/23 paras.35 to 38	CX/MAS 01/04 – add2
24th Session 18 - 22/11/2002	ALINORM 03/23	CX/MAS 02/04-Add 2; CRD 17
25th Session 08 – 12/03/2004	ALINORM 04/27/23 paras. 55 to 58	No new documents