codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 2 **CX/FICS 03/2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Twelfth Session

Brisbane, Australia, 1 – 5 December 2003

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

1. GENERAL DECISIONS OF THE COMMISSION

1.1 AMENDMENTS TO THE PROCEDURAL MANUAL[1]

Clarification of Rule VI.4 (Voting and Procedures)

1. The Commission amended Rule VI.4 on Voting and Procedures to include a reference to Rule X.2 related to the adoption or amendments of Codex standards by consensus.

Membership of Regional Economic Integration Organizations

2. The Commission amended the Rules on Membership to allow regional economic integration organizations to exercise rights of membership within the Codex Alimentarius Commission and its subsidiary bodies under specific conditions.

Measures to Facilitate Consensus

3. The Commission adopted the *Measures to Facilitate Consensus* for inclusion in the Procedural Manual as a general decision of the Commission.

Principles for the Establishment of Methods of Analysis

4. The Commission adopted the amendment to the *General Criteria for the Selection of Methods of Analysis using the Criteria Approach* and the new section addressing *Working Instructions for the Implementation of the Criteria Approach in Codex*.

1.2 RISK ANALYSIS[2]

5. The Commission adopted the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* and the definitions related to risk analysis.

6. The Commission requested that **relevant Codex Committees develop or complete specific guidelines on risk analysis in their respective areas**, for inclusion in the Procedural Manual, as recommended in the Action plan adopted by the 22nd session of the Commission. The Commission noted that these texts would be submitted to the Committee on General principles in order to ensure coordination of work and consistency with overarching Working Principles.

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1 ALINORM 03/41, paras. 15-31 and Appendices II and III.

2 ALINORM 03/41, paras. 146-147 and Appendix IV and Procedural Manual, 13th Edition

1.3 JOINT FAO/WHO EVALUATION OF THE CODEX ALIMENTARIUS AND OTHER FAO AND WHO WORK ON FOOD STANDARDS

7. The Commission took several decisions concerning the implementation of the recommendations of the Evaluation, enacting some immediately and requesting the Codex Committee on General Principles to draft the amendments to the Procedural Manual required implementing others. Some selected decisions are summarized below. Further details on this matter can be found in the report of the 26th Session of the Codex Alimentarius Commission.[3]

1.3.1 General Aspects

Annual meetings of the Commission

8. The Commission agreed to meet annually for the next two years, but that in future each session would consider the timing for the following session and the general nature of the agenda in order to achieve the appropriate balance between standards issues, general direction of work and policy matters, and taking into account the resources available for adequate participation.

Implementation of the Evaluation

9. The Commission decided that the responsibility for following up and monitoring progress in the implementation of the recommendations from the Evaluation Report would be entrusted to the Executive Committee. Twice-yearly sessions of the Committee would be scheduled in order to absorb the additional workload.

Priorities for implementation

10. The Commission decided that the priorities should be:

(a) Processes for standards management, with due regard to the special needs of developing countries.

(b) Functions and composition of the Executive Committee, including the participation of observers in the Executive Committee and Executive Committee procedures.

(c) Review of the Committee structures and mandates (including Regional Committees).

(d) Review of Rules and Procedures including guidelines for Codex Committees.

11. The Commission concluded that all four priorities were of equal importance, and that the ranking was made on the grounds of speed of potential progress.

1.3.2 Review of Codex Committee Structure and Mandates of Codex Committees and Task Forces, including Regional Committees

12. The Commission decided that all the Committees and Task Forces would be reviewed together bearing in mind the objective of reducing the number of meetings while also keeping them short and focused. The Commission endorsed the recommendation made by the Executive Committee concerning the selection of consultants that would be entrusted with the review,[4] and stressed the critical importance of transparency in the process.

1.3.3 Improved Processes for Standards Management

Critical review of proposals to undertake work and monitoring progress of standards development

13. The Commission decided to endorse the critical review process, including the preparation of project documents for major standards as well as the closely related proposal to revise the Criteria for the Establishment of Work Priorities in order to ensure the relevance of Codex standards at the international level.

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3 ALINORM 03/41, paras. 149-183

4 ALINORM 03/4, para. 23.

Standards management responsibility

14. The Commission decided that the Executive Committee be the body to undertake the critical review of new work. The Commission did not favour the replacement of the Executive Committee with an Executive Board.

Time-bound decision-making

15. The Commission decided that the body responsible for standards management (i.e. the Executive Committee) should review the status of development of draft standards at the end of a specified time-frame, normally not more than five years, and report its findings to the Commission. The time-frame could be less than five years, where this was appropriate or had been established during the critical review process for new work.

Simplified procedures for standards development

16. The Commission decided to retain the 8-Step process, with the existing mechanisms to accelerate the process when necessary.

Use of facilitators and Establishment of electronic and/or physical working groups

17. The Commission agreed in principle to all three proposals but decided that the modalities would require clarification by the body responsible for reviewing the Procedural Manual. With respect to electronic working groups, the Commission noted that these were an avenue for exchanging views and not for decision making. Physical working groups should be ad hoc, open to all members, take account the problems of developing country participation and only be established where there is consensus in the Committee to do so and other strategies have been considered.

Adoption of Standards

18. The Commission decided that adoption of standards with a limited amendment should be allowed, provided that the draft standard had been forwarded to the Commission on the basis of consensus, based on the recommendation of the Executive Committee.

1.3.4 Review of the Rules of Procedure and Other Procedural Matters

Responsibility for the Procedural Review

19. The Commission decided that the procedural review would be undertaken by the Codex Committee on General Principles, at special sessions and under a limited time-frame. The Commission agreed that the Committee would need clear instructions, terms of reference from the Commission and support from the Codex Secretariat.

Amendment of the Codex Mandate

20. The Commission decided that the current Codex Mandate as expressed in Article 1 of the Statutes of the Commission, should be retained but that it might be discussed in the future.

Criteria for the establishment of work priorities

21. The Commission requested the Codex Committee on General Principles to redraft the *Criteria for Work Priorities* to reflect the current priorities of the Commission and in a manner that would provide explicit judgment tools for assessing work proposals against priorities.

1.4 FAO/WHO TRUST FUND FOR PARTICIPATION OF DEVELOPING COUNTRIES IN CODEX STANDARD SETTING PROCEDURES

22. The Commission welcomed the progress made on the FAO/WHO Trust Fund for Participation of Developing Countries in Codex Standard Setting Procedures and expressed the hope that it would achieve the desirable threshold before the end of 2003, so that it would be operational by the time of the next Session of the Commission.[5]

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[5] ALINORM 03/41, para. 189

2. DECISIONS OF THE COMMISSION CONCERNING THE WORK OF THE COMMITTEE

2.1 CONSIDERATION OF DRAFT STANDARDS AND RELATED TEXTS AT STEP 8 [6]

Guidelines for Food Import Control System

23. The Commission considered a proposal from the Delegation of Paraguay to the effect that the phrase "a reasonable interval" in paragraph 35 of the Guidelines was open to misinterpretation and should be clarified by the inclusion of a reference to "a previously agreed interval or period of time". Several delegations noted that the text as proposed by the Committee on Food Import and Export Inspection and Certification Systems was consistent with the text of the WTO SPS Agreement, and also noted that the **Committee would consider the development of an interpretation of the meaning of "a reasonable interval" as new work**. The Delegation of Switzerland also stressed the need for the term "Control Systems", as used in the guidelines, to be defined, as indicated in the EU comment. But this should not hold adoption of the Guidelines. The Commission adopted the Guidelines as proposed.

Guidelines for the Judgement of Equivalence of sanitary Measures Associated with Food Inspection and Certification Systems

24. The observer from the WTO drew the attention of the Commission to parallel work being undertaken within the WTO Committee on Sanitary and Phytosanitary Measures and stressed the importance of finalizing these Guidelines in order to assist countries in implementing the equivalence provisions of the SPS Agreement. The Delegation of Switzerland noted that, in its opinion, the definition of sanitary measures went beyond the Codex mandate.

25. The Delegation of The Republic of Korea stated that the Section of the Guidelines dealing with the *Procedure for the* Determination *of Equivalence* did not contain sufficient information to enable the implementation of the Guidelines to the control of food trade and required further elaboration. The Delegation of Peru stated that it considered that the Section dealing with the General Principles for the Determination of Equivalence was subjective and required further clarification.

26. The Commission adopted the Guidelines as proposed and noted that **the matters raised by the Delegations of Korea and Peru would be further considered by the Committee at its next meeting**.

2.2 DISCONTINUATION OF WORK [7]

27. The Commission approved the recommendation of the Committee Food Import and Export Inspection and Certification Systems to discontinue work on the elaboration of the proposed draft *Guidelines for the Utilization and Promotion of Quality Assurance Systems to meet Requirements in Relation to Food*.

3. OTHER CODEX COMMITTEES

3.1 TRACEABILITY/PRODUCT TRACING

Codex Committee on General Principles

28. The eighteenth Session of the Committee on General Principles (April 2003) considered a document on Traceability/Product tracing, prepared by the Codex Secretariat, which contained several options to take in pursuit of this matter. The Committee concluded that there was sufficient support only to proceed with the development of a definition of "traceability/product tracing" for Codex purposes and agreed to establish an open-ended electronic working group under the delegation of France to develop a draft for the consideration of the next regular Session of the Committee (May 2004).

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6 ALINORM 03/41, paras. 61-65 and Appendix V

7 ALINORM 03/41, para. 211

29. In view of the divergence of opinions on the other options contained in the Secretariat's paper, the Committee was unable to a arrive to a consensus opinion, but agreed to keep the matter under review in the light of the ongoing work in the Codex Committee on Food Import and Export Inspection and Certification Systems.[8]

Ad hoc Intergovernmental Codex Task Force on Food Derived from Biotechnology

30. The 4th Session of the *Ad Hoc* Intergovernmental Codex Task Force on Foods Derived from Biotechnology (March 2003) conducted an open discussion on traceability. The main elements of the discussion included: consideration of traceability had started in this Task Force and there was consensus to continue further discussion in the framework of Codex; traceability or product tracing was an important element to ensure food safety throughout the food chain; it could address the request of consumers for transparency and improved information; and its implications for developing countries should be further considered, especially to ensure fair trade. [9]

Codex Committee on Food Labelling

31. The thirty-first Session of the Codex Committee on Food Labelling (April 2003) continued the discussion initiated at its previous Session on whether or not and if so how the Committee would proceed with work on traceability, based on a background document prepared by Canada presenting current discussions in various Codex Committees. It agreed to continue the discussion on traceability/product tracing at the next Session (May 2004) taking into account the progress made by other Committees. [10]

Ad hoc Intergovernmental Codex Task Force on Animal Feeding

32. The 4th Session of the Codex *Ad Hoc* Intergovernmental Task Force on Animal Feeding forwarded the proposed draft Code of Practice on Good Animal Feeding to the 26th Session of the Codex Alimentarius Commission for final adoption at Step 5/8 (with the omission of Step 6 and 7).[11]

33. Noting the lack of consensus on some controversial issues, i.e. definition of feed additives; the labelling of feed containing GMOs; and the requirements for traceability/product tracing of animal feeds and feed ingredients, the Commission adopted the proposed draft Code on Good Animal Feeding at Step 5 and advanced the text to Step 8 (with the omission of Steps 6 and 7), with the exception of the definition of "feed additive" and paragraphs 11, 12 and 13 that were advanced to Step 6 only for further consideration by an additional session of the *ad hoc* Task Force on Animal Feeding. The Commission agreed that the Task Force would not consider any other issues. The text that had been advanced to Step 8 was held at that Step by the Commission pending finalization of the outstanding issues.[12]

3.2 USE OF ANALYTICAL RESULTS

Codex Committee on Methods of Analysis and Sampling

34. The twenty-fourth Session of the Committee on Methods of Analysis and Sampling (November 2002) considered a document on the *Use of Analytical Results: Sampling, Relationship Between the Analytical Results, the Measurement Uncertainty, Recovery Factors and the Provisions in Codex Standards.*

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8 ALINORM 03/33A, paras. 85-98
9 ALINORM 03/34A, paras. 64-80
10 ALINORM 03/22A, paras. 120-125
11 ALINORM 03/38A, para. 65
12 ALINORM 03/41, para. 41

35. 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.

36. The Committee agreed to forward the document to Commodity Committees for their consideration and comments. The Committee also agreed to forward it to the Committee on Food Import and Export Inspection and Certification Systems and ask its advice insofar as inspection issues were involved.[13]

37. The Committee **is invited to comment** on the document, annexed to this paper.

3.3 MODEL EXPORT CERTIFICATE

Codex Committee on Milk and Milk Products

38. The fifth Session of the Codex Committee on Milk and Milk Products (April 2002) agreed to the elaboration of a proposed draft *Model Export Certificate for Milk and Milk Products*[14] and requested a drafting group led by Switzerland to elaborate the model certificate for circulation, comments and additional consideration at its 6th Session (April 2004). The working document prepared by the drafting group has been circulated for comments under reference CX/MMP 04/06/9 with a comments deadline of 27 February 2004.

Codex Committee on Fresh Fruits and Vegetables

39. The eleventh Session of the Codex Committee on Fresh Fruits and Vegetables (September 2003) considered proposed draft *Guidelines for the Quality Control of Fresh Fruits and Vegetable*s which contains a *Certificate for the Conformity of Fresh Fruits and Vegetables* and agreed to return the proposed draft to Step 2. It further agreed that a drafting group led by Canada would revise the text on the basis of the written comments submitted and the discussion at the current Session for circulation, comments and further discussion at its next Session (May 2005). [15]

Codex Committee on Fish and Fishery Products

40. The twenty-sixth Session of the Codex Committee on Fish and Fishery Products (October 2003) agreed to advance the draft *Model Certificate for Fish and Fishery products (Sanitary Certificate*) to Step 8 for final adoption by the twenty-seventh Session of the Codex Alimentarius Commission. [16]

41. The Committee agreed that there was no need for further work on other certificate and agreed to discontinue work on the elaboration of proposed draft *Model Certificates (Other Certificates)*.[17]

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13 ALINORM 03/23, paras. 109-117
14 ALINORM 03/11, para. 121
15 ALINORM 04/27/35, para. 86
16 ALINORM 04/27/18, para 68 and Appendix III
17 ALINORM 04/27/18, paras. 69-70

3.4 QUALITY CONTROL

Codex Committee on Food Hygiene

42. The twenty-fifth Session on the Codex Committee on Food Hygiene (January 2003) considered proposed draft *Guidelines for the Validation on Food Hygiene Control Measures* for eventual inclusion as an annex to the International Code of Practice – General Principles of Food Hygiene on the basis of a document prepared by the United States. In presenting the proposed draft Guidelines, the delegation of the United States noted that the Guidelines were intended to meet the need for asssurances that a single point or the entire food safety control system met their objectives. It was noted that the Guidelines should be consistent with a risk analysis framework, including the verification of the public health outcome. The Committee decided not to discuss the proposed draft Guidelines in detail and focussed its discussions on matters to be considered by the drafting group so as to provide general guidance.

43. Although it was suggested that the much broader International Organization for Standardization definition for validation might be taken into account in order to avoid confusion within the industry, the Committee agreed that the current Codex definition for validation contained in the HACCP Guidelines was a long-standing specific defintion related to food safety. However, it was also noted that validation was not limited to the evaluation of control measures within the HACCP system and that the document might need to be expanded to address the evaluation of other food hygiene control measures.

44. In view of the discussion, the Committee agreed that the scope of the Guidelines, as well as the definition for validation might need to be expanded to any control systems related to food hygiene control measures. The Committee decided that the document should be revised on the basis on the discussion and written comments submitted for further consideration at its next meeting.[18]

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[18] ALINORM 03/13A, paras. 157-164

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Agenda Item 9 **CX/MAS 02/13**

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

Twenty-fourth Session
Budapest, Hungary, 18-22 November 2002

THE USE OF ANALYTICAL RESULTS: SAMPLING, RELATIONSHIP BETWEEN THE ANALYTICAL RESULTS, THE MEASUREMENT UNCERTAINTY, RECOVERY FACTORS AND THE PROVISIONS IN CODEX STANDARDS

(Prepared by the United Kingdom)

INTRODUCTION

It was noted at the 23rd Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS) that there were a number of decisions that may be taken by those responsible for the enforcement of Codex specifications which directly affect decisions as to whether a lot is in compliance with a Codex specification (see ALINORM 01/23, paras 60 and 64).

It was therefore proposed that a paper be prepared outlining the issues involved. This paper describes the issues and makes recommendations and guidance to governments that could be included in Volume 13 of the Codex to aid the development and subsequent enforcement of Codex Commodity standards.

This paper is written in a form such that the issues identified could be readily appreciated by Codex Commodity Committees.

Issues Involved

There are a number of analytical and sampling considerations which prevent the uniform implementation of legislative standards; these are addressed in this paper. In particular the problems of:

1. the basic principles of the sampling procedures used by the Member States of Codex to enforce Codex Standards (see Annex I)
2. the treatment of analytical variability (normally known as the measurement uncertainty) in the interpretation of a Codex specification (see Annex II), and
3. the use of recovery corrections when calculating and reporting analytical results (see Annex III).

are addressed in the Annexes. The effect of different countries taking different approaches for each of the issues identified are described.

It must be appreciated that there may be other enforcement issues which have a similar effect.

These aspects directly affect the interpretation of results in countries which use Codex Standards and so may be regarded as "food control". At the present time there is no common interpretation of analytical results across the Codex Community so significantly different decisions may be taken after analysis of the "same sample". Material for which there is a statutory limit of, say, 4μg/kg for a contaminant may be interpreted as containing 3μg/kg on analysis in one country but 10μg/kg in another. This is because some countries correct analytical results for recovery, others do not; some countries use an "every-item-must-comply" sampling regime, others may use an "average of a lot" regime.

It is essential that interpretation of analytical results is similar if there is to be equivalence across the Codex Community; without it there is no uniform interpretation of Codex standards.

It is stressed that this is not an analysis or sampling problem as such but an administrative problem which has been highlighted as the result of recent activities in the analytical sector, most notably the development of International Guidelines on the Use of Recovery Factors when Reporting Analytical Results, and various Guides prepared dealing with Measurement Uncertainty.

The effects are addressed in the Annexes to this paper.

SOLUTION

It is important that delegates to Codex Commodity Committees realise that different actions taken with respect to the above consideration have a significant difference on the "enforcement" of the Codex Provisions. Because the effect is so marked, it is important that delegates to Commodity Committees are aware that there is the possibility that different countries will "interpret" the commodity standard with respect to compliance of a lot in different ways. It is therefore recommended that when Codex Commodity Committees negotiate specifications they do so with respect to those factors which affect the interpretation of the Codex specification. In addition the Commodity Committee should give clear simple guidance to CCMAS with respect to how it wishes the Codex specification to be "enforced". This guidance is to cover both sampling plans and aspects of the analytical enforcement of the commodity specifications.

RECOMMENDATIONS

It is recommended that at the same time that the Codex Commodity Committee discusses and agrees a commodity specification, it states the following information:

Sampling

The principle on which any sampling plans are to be developed, and in particular whether any detailed plans subsequently developed by CCMAS are to be on the basis that the specification applies to every item in a lot or to the average in a lot, and the appropriate acceptable quality level to be used.

Measurement Uncertainty

Whether allowance for the measurement uncertainty is to be made when deciding whether an analytical result falls within the specification or not.

Recovery

Whether the analytical result of a lot is to be reported on a recovery corrected or uncorrected basis.

Although each of the above attracts a number of scientific considerations, it is of prime importance that all Codex countries adopt the same approach so that a common approach to enforcement of Codex standards is taken.

ANNEX I: INFORMATION FOR CODEX COMMODITY COMMITTEES ON THE SELECTION OF CODEX SAMPLING PROCEDURES AND INTERPRETATION OF CODEX SPECIFICATIONS

INTRODUCTION AND GENERAL BACKGROUND

Codex sampling plans are designed to ensure that fair and valid procedures are used when food is being tested for compliance with a particular Codex commodity standard. The sampling procedures are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in the light of the relevant provision(s) of the applicable Codex Standard.

Codex Committees should, when developing provisions (characteristics) in a Standard, relate the numerical value of the characteristic, the associated method of sampling and the method of analysis to one another. The Codex General Principles for Analysis and Sampling (Codex Alimentarius Commission, Procedural Manual, Tenth Edition) are intended to ensure that this will be done when selecting Codex methods of sampling and analysis for inclusion in Codex Standards. This requirement is generally followed when methods of analysis are to be developed but, regretfully, infrequently when methods of sampling are to be elaborated.

This is generally because the importance of the relationship is not always understood or is considered to be too complex; this paper is intended to demonstrate that the significance of the relationship and thus encourage Codex Commodity Committees to address the sampling requirements in their Standards.

Specification Limit and Interpretation of Results

It is important that a Codex Commodity Committee considers and then defines exactly how the specification is to be interpreted. Without this information it is difficult to develop the methods of sampling and analysis which are then to be used to interpret the specification. This may be best illustrated by the example below:

Let us assume that a lot of 1,000 units of, say, a foodstuff is to be investigated to ascertain whether it is in compliance with a Codex specification of 2 mg/kg lead.

If each of the 1,000 units were to be sampled and analysed for its lead content, then the distribution of lead in the individual units may be shown diagrammatically below:

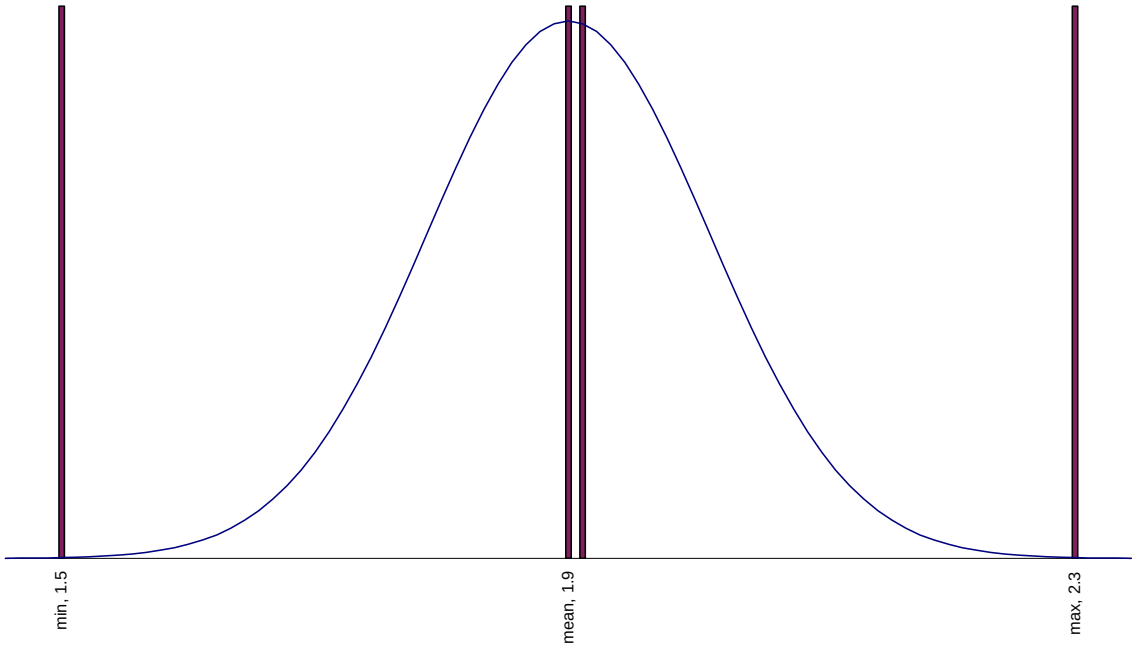

Figure: plot of the distribution of lead in the 1,000 units, with minimum concentration of 1.5 mg/kg, mean concentration in the lot of 1.9 mg/kg and maximum concentration of 2.3 mg/kg. The specification limit is 2 mg/kg.

Two countries may have different national rules for the interpretation of results from lots.

Country A requires: that each and every item in the lot meets the specification. In this example it means that all 1,000 units, if analysed separately, would have to be less than 2.0 mg/kg. Here a significant number of units are greater than 2.0 mg/kg so the lot would be deemed to be in non-compliance with the Codex specification and so would be rejected, but

Country B requires: that the mean value of the characteristic in the lot is to be less than the Codex specification. In this case the mean value is 1.9 mg/kg so the lot would be deemed to be in compliance with the Codex specification.

Consequence:	the two countries A and B will make different judgements as to compliance with a Codex specification on essentially the same lot. This is unacceptable and can only be avoided if the sampling procedures are elaborated at the same time as the commodity standard is elaborated in the Commodity Committee. In addition it should also be noted that the number of units to be analysed also influences the decision on compliance (see below).

The approach to be taken must be defined before any sampling procedure is discussed. At present there is no information given as to the basis on which the Codex specification is to be evaluated prior to discussions on sampling commencing. This creates severe difficulties when methods of sampling are developed. The procedure for the analysis of the individual sample units is now well defined within Codex, but the framework within which the results are to be used is not.

Relationship Between Value of a Characteristic in a Commodity Standard and Methods of Analysis and Sampling Used for its Estimation

Before any characteristic in any Codex Standard is elaborated it must be appreciated that the value of the characteristic in that Codex Standard is dependent on the procedures used to estimate that value. In particular, the estimate of the value may be dependent upon the method of analysis used, but is always dependent on the method of sampling used to verify compliance with the Standard. It is important for delegates at Codex Commodity Committees to appreciate the influence that methods of analysis and sampling may have on the judgements that may be made with regard to the compliance of a lot with respect to a Codex Commodity Standard. Without common and uniform methods of analysis and sampling procedures different authorities will make different judgements as to whether any particular lot is compliance with its Codex specification, as has been illustrated above. The relationship between the value of a characteristic in a Codex Commodity Standard and the method of analysis to estimate that value can be readily appreciated, but the link between the value of the characteristic and the method of sampling is less well understood.

This is best illustrated by example, taking first methods of analysis, and then methods of sampling.

Methods of Analysis

This may be best illustrated by reference to the “types” of methods of analysis which have been adopted by the Codex Alimentarius Commission. The CAC has stated that as Type I methods “define” the value of the characteristics in the Standard only a single Type I method can be prescribed. Methods of analysis for “fat” are Type I methods. It is possible to determine the “fat” content in a sample by two equally validated methods of analysis, each conforming to a different analytical principle. As a consequence the application of these two methods to the same sample will result in two different, but equally valid, results. In order to remove this possibility the Codex system only allows the adoption of a single Type I method.

In addition it is a mandatory requirement to accept the Type I Codex method if the Standard itself is to be accepted - i.e. the separation of the value of the characteristic and the relevant Type I method is, in effect,

meaningless. It has, therefore, been agreed by the Codex Committees on Methods of Analysis and Sampling and on General Principles that non-acceptance of the Codex defining methods, or acceptance of Codex Standards with substantial deviations in the Codex defining method, should be taken to mean acceptance of the Codex Standard with a specified deviation.

Codex Type II and III methods determine the content of a defined chemical entity and these methods may be used interchangeably depending upon the particular situation except that Type II Codex methods are intended to be obligatory in cases of disputes concerning the results of analysis. However this approach may be modified as a result of the present discussions on the introduction of a criteria (performance-based) approach to methods of analysis in Codex Commodity Standards.

Methods of Sampling

The same considerations as apply to methods of analysis also apply to methods of sampling. This may also be best illustrated by a simple example.

One of the criteria by which the quality of a lot may be judged is the acceptable quality level (AQL) for a specification in a lot. In simple terms, the acceptable quality level in a lot is the percentage of defective items that is considered satisfactory as a process average and is accepted with a given high probability of acceptance (usually in the region of 95%). For a specification in a batch two countries may have different acceptable quality levels i.e.

Country A may prescribe an acceptable quality level of 0.1%, i.e. it will only accept a batch if 99.9% of the product meets the specification whereas

Country B has prescribed an AQL of 10%, i.e. that country will accept the batch if 90% of the product meets the specification.

The amount of sampling and the commodity specification required to determine these two batches is different in each case and thus there is no harmonisation of sampling. If left undefined these two countries could make different judgements as to whether a particular lot would comply with a Codex specification.

One of the critical aspects of sampling is that numbers of units must be taken at random throughout the batch. This is often difficult to achieve and the approach to randomisation will produce different decisions as to compliance or non-compliance of a batch. It is therefore important that if a uniform approach to sampling is to be taken, that procedures for randomisation are carefully defined.

This, and similar, procedures must be defined **before** sampling plans are discussed.

TIMING OF THE DEVELOPMENT OF SAMPLING AND ANALYSIS PROCEDURES

It has been illustrated above that the type of sampling plan and the lot acceptance procedure used affects whether a lot may be deemed to be in compliance with its specification. It is therefore necessary that when characteristics within a Standard are elaborated, the sampling and lot acceptance procedures to be prescribed to verify those characteristics are also considered at the same time, so that the characteristics are related to the procedures.

It is important to recognise that without general instructions being given to those preparing Codex sampling plans, non-equivalent interpretation of Codex Commodity Standards will occur, thus giving the potential for trade disputes.

To define a numeric value in a Standard is not enough: its interpretation also needs to be defined.

ANNEX II: REPORTING OF RESULTS WITH RESPECT TO THEIR MEASUREMENT UNCERTAINTY

All analytical results should be reported in the form "a ± b" where "a" is the best estimate of the true value of the concentration of the measure and (the analytical result) and "b" is the range within which the true value is estimated, with a given probability, to fall. The value of "b" is known as the "measurement uncertainty" and may be estimated by the analyst in a number of different ways. Even though this terminology is considered suspect by some, it is now internationally accepted.

The estimation of the value of "a" is dependent on:

- the accuracy of the method of analysis used
- how well the analyst uses that method, i.e. whether the analytical system is "in control".

The value of the measurement uncertainty "b" is dependent on:

- the inherent precision of the method of analysis used
- the number of analytical replicates that are carried out. The more replicates the less the value of the measurement uncertainty.

REPORTING OF RESULTS BY FOOD CONTROL ANALYSTS

The procedure adopted by some food control analysts is to report samples as containing "not less than "a" – "b"" in situations where the statutory limit is a maximum permissible concentration. Thus, in any enforcement situation the maximum benefit is given to the food producer. This is consistent with the requirement to prove ***beyond reasonable doubt*** that a limit has been exceeded, if the case should come to Court. This does mean that the effective enforcement limit is, in such countries, not identical to the numerical value given in the Codex specification.

Other food analysts may report the value "a" without taking into account any measurement uncertainty considerations.

CONSEQUENCES OF REPORTING RESULTS IN DIFFERENT WAYS

There are potential problems with the reporting of results for which there is a Codex specification.

This is best explained by example:

Let us assume that there is a Codex specification of 4 μg/kg for the analyte being analysed. It would be anticipated that the measurement uncertainty for the analysis will be of the order ± 45% of the analytical result, i.e. the analyst would determine for nominal concentrations of 3, 6 and 10 μg/kg, the following concentrations including their uncertainties:

a. 3.0 ± 1.3 μg/kg,

b. 6.0 ± 2.6 μg/kg, and

c. 10.0 ± 4.4 μg/kg

Situation a

Here the level reported is below the Codex specification. All countries would take the same view and accept the material.

Situation b

Here the level reported is above the statutory limit but the true value lies in the range 3.4 to 8.6 μg/kg. The level and its uncertainty would be reported.

Here some countries would report the sample as containing not less than 3.4 μg/kg of the analyte and because it is not beyond reasonable doubt that the limit has been exceeded, no action will be taken.

However, other countries may take action on the 6.0 μg/kg result, without taking uncertainty into account. For these countries, the material will be deemed to be non-compliant.

Situation c

Here the level reported is above the Codex specification and the true value lies in the range 5.6 to 14.4 μg/kg. All countries will state that the material is non-compliant with the Codex specification.

Conclusion

In situation b there is the possibility that different countries will make opposite decisions as to whether the material conforms with the Codex specification. The approach to be used must be indicated by the Codex Commodity Committee when negotiating the Codex Commodity Standard.

ANNEX III: USE OF RECOVERY INFORMATION IN ANALYTICAL MEASUREMENT

CCMAS has discussed the harmonisation of reporting of test results corrected for recovery factors. In particular it has adopted by reference the "Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement", published by IUPAC. However, it did not adopt by reference the first two sentences of the first Recommendation, namely "Quantitative analytical results should be corrected for recovery unless there are specific reasons for not doing so. Reasons for not estimating or using correction factors include the situations where (a) the analytical method is regarded as empirical, (b) a contractual or statutory limit has been established using uncorrected data, or (c) recoveries are known to be close to unity."

The next three sentences of Recommendation 1 are also important, these being:

"However, it is of over-riding importance that all data, when reported, should (a) be clearly identified as to whether or not a recovery correction has been applied and (b) if a recovery correction has been applied, the amount of the correction and the method by which it was derived should be included with the report. This will promote direct comparability of data sets. Correction functions should be established on the basis of appropriate statistical considerations, documented, archived and available to the client."

The above serves to indicate the importance of recovery corrections and, as in the previous Annexes, one can obtain a similar situation where different countries may report a different analytical result depending upon whether a recovery correction has been made or not.

A real example may result in the mycotoxin area where there may be a limit of 4μg/kg for total aflatoxin in nuts. Here the following situation may arise: Country A will analyse a consignment and find a result of 3.5μg/kg total aflatoxin using a method which, in the analytical run, has a recovery of 70%. Country A does not correct for recovery corrections as a matter of policy and so the reported result will be 3.5μg/kg and so the sample will be in compliance with the 4μg/kg limit.

Country B, however, uses recovery corrections as a matter of policy. That country could analyse the "same" sample using the "same" methodology and obtain the "same" analytical result but will report not 3.5 but 5μg/kg on a recovered basis. Here there is the possibility that because the 5μg/kg level is greater than the Codex limit of 4μg/kg limit for total aflatoxin that country may deem the sample not to be in compliance with the Codex limit.

As in the previous situations it is important that the Codex Commodity Committee stipulates the basis on which the Codex specification is to be enforced.