

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

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Agenda Item 2

CX/MAS 04/2-Add.1

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Twenty-fifth Session

Budapest, Hungary, 8 – 12 March 2004

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

THE USE OF ANALYTICAL RESULTS: SAMPLING, RELATIONSHIP BETWEEN THE ANALYTICAL RESULTS, THE MEASUREMENT UNCERTAINTY, RECOVERY FACTORS AND PROVISIONS IN CODEX STANDARDS¹

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).

A paper was prepared for the 24th Session of CCMAS which outlined the issues involved (see CX/MAS 02/13). That paper described 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.

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

It was agreed at the 24th Session of CCMAS to forward that document containing explanatory notes 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.

OTHER COMMITTEES COMMENTS FROM OTHER CODEX COMMITTEES

The document was circulated to other Codex Commodity Committees (see CX/MAS 04/2).

The essential comments made by other Committees are:

Committee on Fats and Oils

The Committee agreed that the concepts described in the paper should be addressed in order to ensure a uniform approach to the development and application of Codex standards. It recommended that instructions with respect to analytical compliance be developed for all Commodity Committees by the Codex Alimentarius Commission or another appropriate horizontal Codex Committee.

¹ Prepared by the United Kingdom, for consideration in conjunction with Matters Referred from Other Codex Committees (CX/MAS 04/2) on the Use of the Analytical Results

Committee on Fish and Fishery Products

The Committee agreed that the concepts put forward in the document should be taken into account in future work on standards under consideration, such as bivalve molluscs that included biotoxin and microbiological limits. It also agreed that the Committee on Methods of Analysis and Sampling should continue its work to provide guidance for Commodity Committees in this area.

Committee on Food Import and Export Inspection and Certification Systems

The Committee agreed on the importance of the document in the development of Codex specifications and its relationship with the sampling procedures, interpretation of analytical results, and compliance/rejection of lots of products. It encouraged the CCMAS to continue to work on this issue in a more general way with a view to advising Codex commodity committees and governments about matters related to methods of analysis and sampling and the development and enforcement of Codex commodity standards.

Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices

Measurement Uncertainty: An allowance for measurement uncertainty should be made when deciding whether an analytical result fell within a specification or not.

Recovery: Analytical results for quality, composition and authenticity should not be corrected for recovery.

POSSIBLE GUIDELINES

Delegates to the 24th Session of CCMAS and to a number of other Codex Committees have agreed that this subject is important and so should be addressed.

In the light of these responses draft Guidelines on the use of analytical results: sampling, relationship between the analytical results, the measurement uncertainty, recovery factors and the provisions in Codex Standards have been prepared for discussion at the Twenty-fifth Session of CCMAS. They are given at Annex I of this paper.

RECOMMENDATIONS

It is recommended that these draft Guidelines are discussed with a view to their eventual adoption by the Codex Alimentarius Commission.

The development of such Guidelines are a continuation of work already in the work programme of CCMAS.

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

Issues Involved

There are a number of analytical and sampling considerations which prevent the uniform implementation of legislative standards, and in particular different countries may take different approaches to each of the following issues:

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

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, some deduct the measurement uncertainty associated with the result, others do not.

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.

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. It is recommended that the specification be developed on the assumption that it will apply to the average in a lot.

Measurement Uncertainty

Whether allowance for the measurement uncertainty is to be made when deciding whether an analytical result falls within the specification or not. It is recommended that the specification be developed on the assumption that the measurement uncertainty will be taken into account (i.e. when deciding whether an analytical result meets the specification or not the “beyond reasonable doubt” principle shall be used).

Countries shall use the measurement uncertainty associated with an analytical result when deciding whether an analytical result falls within the specification or not for food control purposes. The way that measurement uncertainty is to be used by Countries must be taken into account when analytical specifications are discussed. In practice, the analyst will determine the analytical level and estimate the measurement uncertainty at that level. The value obtained by subtracting the uncertainty from the reported concentration, is used to assess compliance. Only if that value is greater than the maximum level in legislation, it is sure “beyond reasonable doubt” that the sample concentration of the analyte is greater than that prescribed by legislation.

Recovery

Whether the analytical result of a lot is to be reported on a recovery corrected or uncorrected basis, whether recovery should be quoted, and any minimum and/or maximum recovery deemed acceptable. It is recommended that the specification be developed on the assumption that the recovery will be taken into account.

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.