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 6 **CX/MAS 05/26/8**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

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

GOVERNMENT COMMENTS
(Mexico, United States)

MEXICO

SAMPLING : As commented in CX/MAS 03/13 the considerations that apply to methods of analysis should also apply to sampling methods, since the analytical result may be validated in all the meaning of the term but the analytical result may be non representative of the whole. In general terms, the following statistical parameters should be taken into account in sampling methods.

With the confidence limits for the means and the tolerance interval for a specified percentage of the components of the population, the number of samples should be established to establish the above intervals with a specified level of significance. In view of the above, sampling should be independent and samples should be selected randomly from the relevant population. The type of distribution of samples should be known in order to apply the correct statistical model.

PERCENTAGE OF RECOVERY: the percentage of recovery is a very important parameter. In the validation of the method it contributes to ensuring the approximation of the mean value with the conventionally true value. When this value is validated above 90% for raw material analysis, process and end product control do not need to be taken into account since it is included in the specification intervals of the analyte to be determined, as for example from 90 to 100%. However, in the analysis of residues or contaminants where allowed limits are specified on the basis of the risk for human health and all living beings, there should be a correction for recovery. It is fundamental to take into account that this factor is always plus and never plus-minus.

UNCERTAINTY: This term is more user-friendly than the recovery percentage and gives the option of a higher or lower mean value, although there is always a doubt. THIS IS THE UNCERTAINTY. Moreover, if the uncertainty factors are analysed, this can be minimized to a value that does not affect the measurand. The ISO Standard requests that the uncertainty be reported in the analytical result.

UNITED STATES

The United States fully supports the need for clear guidance in Codex Standards that enables consistent interpretation of analytical results across the Codex Community. We believe that if the recommendations in this document were adopted by the Commodity Committees there would be a significant improvement in the uniform interpretation of analytical results for determining compliance with Codex Standards.

Our primary concern is that the recommendations section of Alinorm 04/27/23 Appendix VII may not be clear to the Commodity Committees. In order to assist the Commodity Committees in their implementation of the CCMAS recommendations, we suggest that the document should have an example Codex Standard (hypothetical or actual) which illustrates how to include information regarding sampling plans, measurement uncertainty, recovery and significant figures. We also suggest that CCMAS continue work on refining this version and solicit comments from Commodity Committees concerning what would make it most useful to them.