REPORT OF THE 18th MEETING OF INTERNATIONAL ORGANISATIONS WORKING IN THE FIELD OF METHODS OF ANALYSIS AND SAMPLING (INTER-AGENCY MEETING)

Budapest, Hungary 12th May 2006

Present

AAFCO	Nancy Thiex
AOCS	Richard Cantrill (Secretariat)
CEN TC 275	Duncan Arthur, representing Braxton Reynolds
Codex	Eva Deak
	Selma Doyran
EURACHEM	Steve Ellison
FPA	I-Pin Ho
HFSO	Arpad Ambrus (observer)
ICC	Roland Poms
ICUMSA	Roger Wood (Chairman)
IDF	Fred.J.P. Van Luin
	Rinus Van Schaik
IFU	David Hammond
ISO	Pauline Jones
	Rinus Van Schaik
IUPAC	Christoph von Holst , representing Elke Anklam
	Roger Wood
NMKL	Hilde Skaar Norli
OIV	Jean-Claude Ruf

Apologies

Apologies were received from

Alan Hanks (AAFCO, and now to be represented by Nancy Thiex), Robert Wielgosz (BIPM), Braxton Reynolds (CEN TC 275), Mark van Woerden (CEN TC 327), Joerg Seifert (IDF), Nadine Normand (AFNOR) and Elke Anklam (IUPAC)

The attendees were welcomed by Arpad Ambrus, Deputy Director of the Hungarian Food Safety Office, which was kindly hosting the meeting. Dr Ambrus explained the role of the HFSO, which was established in 2003, and which has a co-ordinating function

1. Report of the previous meeting IAM-17, 2005

This was accepted without modification.

2. Matters arising from the previous meeting not otherwise on the agenda

There were none.

3. Criteria Approach

It was noted that as a result of the adoption of the criteria approach by the CAC, users of analytical methods would require more information than was currently included in "Standard Methods". In particular it was noted that IAM "customers" when selecting one of our methods will want information on particular attributes of that method. It was noted that the criteria required by Codex (such as accuracy, applicability, detection limit, quantification limit, precision, recovery, selectivity, sensitivity, linearity etc) should have been assessed in the routine validation of methods of analysis and that the formal results of such validation now need to be made available to the users of the methods if they were working in a sector which has adopted the criteria approach. In addition when the validation work of Standard Methods is being designed, it is essential that the validation should enable an estimation of these parameters to be made.

At the present time few, if any, "Standard Methods" included all such information. This is an issue that will now have to be addressed as the criteria approach has been implemented in the (Codex) food sector. In particular it was noted that most methods now included precision data, but few included recovery data. This was unfortunate when organisations such as Codex placed an emphasis on the use of recovery factors.

The same considerations also applied to LOD/LOQ information.

Most delegates agreed that such information is being determined during the course of Standard Methods development though its importance has not been previously recognised. Therefore this information should be made readily available to the users of the methods.

It was noted that it was now essential to:

- Ensure that such data are collected.
- Publish (or make available) all the validation work undertaken prior to the adoption and publication of the final Standard
- Consider how such method development "history" should be best archived.

Action: Members to identify the practicality of collating and making available such information.

It was also noted that it was often difficult to recruit sufficient laboratories to undertake a full collaborative trial and it would be difficult to obtain estimations of some of the values of method performance parameters. However, members noted that in some sectors, such as trace elements or mycotoxins in foods, this had not proved to be the case and estimates of precision parameters were readily obtained.

It was recognised that the value of single laboratory validation would increase as many methods would not be fully inter-laboratory (collaborative study/trial) validated. This would include information obtained from ruggedness testing. The meeting therefore considered that there was a need for international agreement on minimum requirements, even perhaps analyte/matrix specific numeric values, for such validation work. Some work could be disseminated through a peer-validated system with method information being published through an ISO TS/TR type of procedure. The meeting considered the work outlined in paper CL 2005/44-MAS (to be discussed at the CCMAS 27th Session) to be too complex for the needs of most analysts (see below).

It was also noted that a requirement for measurement uncertainty in analytical results rather than meeting method performance criteria had already been used by some legislative organisations and that this practice may become more widespread with the use of single laboratory validation.

Action: Members to identify the practicality of specifying the performance parameters to be undertaken in single-laboratory validation in their sectors and to estimate the numeric values which could be then associated with them.

It was also noted that although the criteria approach does not apply to empirical methods - it was important that reference materials were used where available to establish individual laboratory bias etc.

4. Published Method Title Collation/Work Programmes Collation/"Newsletter" and Website Update

It was agreed that it is of use and of importance to the users of IAM material that information is made available on the work programmes of the IAM Members. It was also agreed that the submission of this information in a standardised (template) format would be unnecessarily onerous.

It was therefore agreed that IAM members would supply the IAM Secretariat with the following information for posting on the IAM Website:

- All new work programmes in the format supplied by the IAM member.
- Links to work programmes on their websites and to publicly available newsletters and news items of individual IAM members.
- A lists of recently-published standards and provide links to those items on their websites.

Action: Members to supply information identified in the bullet points above.

5. Harmonisation of Analytical Terminology in Accordance with International Standards - Definitions

There was extensive discussion on the above. It was noted that in CCMAS paper CX/MAS 06/27/5 that there was a request for the IAM to also consider this work.

The meeting considered and recommended the following:

- That definitions of analytical terminology be taken out of the CAC Procedural Manual and developed as a Guideline. This would then facilitate completeness and up-dating. The Codex representative indicated that this approach would be feasible.

- That the definitions be given for both Codex Types of Methods (I – IV) and for specific analytical terms.

- That the specific analytical terms would include those currently given in the Procedural Manual and those included in the International Protocols/Guidelines already adopted by Codex by reference.

- That the full reference be given for the definitions.

- That the final paper await the imminent publication (as an FDIS) of the revised ISO 3534 - 2.

The above was communicated to the coordinator Dr M. Sussman (USDA) prior to the 27th CCMAS Session who would take these comments into consideration when preparing his Report to the CCMAS Plenary Session.

It was noted that the list of analytical terms embraced by bullet point 3 above included the following:

- Accuracy
- Applicability (and practicability)
- Bias
- Certified reference material
- Empirical method of analysis
- Error
- Horrat
- Interlaboratory study
- Limit of detection
- Limit of quantification
- Linearity
- Measurement uncertainty
- Precision; repeatability intra-laboratory (within laboratory), reproducibility inter-laboratory (within laboratory and between laboratories)
- Quality assurance
- Rational method of analysis
- Recovery/recovery factors
- Reference material
- Relative uncertainty
- Repeatability conditions

- Reproducibility conditions
- Result
- Robustness (ruggedness)
- Selectivity
- Sensitivity
- Surrogate
- Traceability
- True value
- Trueness
- Validated range

But that the following terms are no longer to be used by Codex and so would not be defined: limit of determination and specificity.

Action: Members to await comments from the 27th Session of CCMAS.

6. Specific (Non Analytical) Definitions

The definition for *trans* fatty acids has been commented on in CX/FL/06/34/9. There are also comments on their measurement given. It was noted by the Codex representative that these issues would be best addressed by CCMAS rather than CCFL and that any comments should be raised through the "Matters Arising" mechanism.

7. CCMAS Paper on Guidelines for Evaluating Acceptable Methods of Analysis/other specific CCMAS papers.

It was agreed that this paper (CL 2005/44-MAS) (to be discussed at the CCMAS 27th Session) is too complex for what was needed by most analysts and that the concepts given are extremely complicated and thus difficult to understand. Some IAM members commented that the paper does not marry with the generally-accepted concepts of the AOAC/IUPAC Harmonised Protocol for Collaborative Studies and ISO 5725:1994.

It was agreed that the simple approach which had previously been discussed by CCMAS should be incorporated into the work identified in Section 3 above.

8. Exchange of Reports and Information/Concerns of Participants

8.1 ICC

The ICC representative outlined the proposed "HARMONY" project which may be able to support IAM activities (the name of the project is to be changed during the commissioning process). This will be an EU funded FP6 "Network of Excellence" and will include NGOs in its membership.

The representative also outlined the function of the ICC taskforce on mycotoxins, where sampling issues have arisen, to the IAM.

8.2 IUPAC

The IUPAC representative gave an update on the development of International Guidelines for the Validation of Qualitative Methods through Collaborative Trials. This was being developed in co-operation with EURACHEM, AOAC, UK-FSA. The requirements for study organisation, the differentiation between qualitative and screening method based on a quantitative result (cut-off values). ELISA, PCR, dipsticks, needed to be determined in terms of the number of laboratories, the use of single paired and pooled results to determine fitness of method .

It was noted that NMKL and other organisations (including ICC and IDF) were also considering these issues. It was also mentioned that there is a need to address pass/fail criteria when using "fingerprints" to determine the authenticity of juices.

8.3 EURACHEM

The representative from EURACHEM updated the meeting on the Uncertainty of Sampling Working Group which is being chaired by Mike Ramsey. It was also noted that the issue would be discussed for the first time in Codex. In that paper the relative uncertainties of sampling and analysis were identified in a number of cases.

The representative also stated that a draft EURACHEM paper on "Compliance" had been circulated for "public" comment. It was noted that the paper tended to use engineering principles and terminology (e.g. - "guard-banding") and information on how to set the size of the guard-band. Although there is an attempt to identify both consumer and producer risks, set statistically, for Codex purposes CCGP agrees that it is important to deduct the uncertainty from an analytical result.

9. Incorporation of change of methods/method corrections in the Codex Alimentarius Commission.

The issue of incorporating changes/replacement/supplementation of methods in Codex Standards was addressed (e.g. the replacement/supplementation of the Kjeldahl method by combustion/ Dumas in Codex Standards) was discussed.

It was agreed that this should be raised at the Codex Methods Endorsement Meeting (where it was agreed that it was for both CCMAS and IAM membership to take the initiatives here).

Action: Members to consider their methods incorporated into existing Codex Standards and to list up-dates when required.

10. Review of Secretariat and Chairmanship

It was noted that the Secretariat of the meeting transferred to AOCS immediately prior to the 17th IAM rather than at its conclusion; therefore the current meeting was to be regarded as the first Session that AOCS held the Secretariatship.

The Chairmanship to the end of the next IAM would be held by Roger Wood in order to maintain continuity.

11. Any Other Business

Items were incorporated in the information given above.

12. Provisional Date of the Next Meeting

The next Inter-Agency meeting will take place on the Friday 16th March 2007 prior to the 28 Session of CCMAS, at Budapest, Hungary (which is scheduled to be 19th to 23rd March 2007), and to start at 14.00 hrs.