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 3 c) **CX/MAS 05/26/5-Add.1**

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
Government Comments
(New Zealand)

NEW ZEALAND

General

The flavour of the proposals it that it is a dispute between laboratories that is in question, which can be resolved by the laboratories themselves, with or without intervention by a third laboratory. The procedures should recognise that in practice regulatory authorities are likely to be involved.

New Zealand also suggests that the procedure needs more technical detail to be workable.

Specific Comments

Introductory section

Disputes arise because of disagreements concerning the compliance status of the product, not merely because of disagreement of results. Compliance status involves the interpretation of test results in terms of measurement error and possibly sampling error, and the use of this term broadens the scope from single-result assessments, that might be typically employed for contaminants, to the type of product assessments described in the Codex *General Guidelines on Sampling*.

The list of possible causes of disagreement over test results is not complete. We suggest some points to be added:

- differences in sample composition of the samples tested due to product inhomogeneity or, for example, changes occurring during the storage of the product.
- the execution of the methods, under-recovery etc

We recommend that laboratories should be advised to establish whether the dispute is actually caused by analytical issues before trying to resolve those issues. In practice one might follow part of this procedure to see whether analytical differences are the cause of the dispute, but one may find that there is no conclusive evidence that analytical issues were the cause. It should not be assumed that analytical differences are always the cause, and that this procedure should be followed completely, if necessary.

We also recommend that, in the recommendations on establishing whether the cause is an analytical issue, non-laboratory issues should be considered. In particular there are statistical issues concerning the interpretation of results, and non-technical matters to be considered (for example the credibility of results indicating apparently high levels of a residue for a pesticide not registered for use in the country that the product was imported from).

Prerequisites

The pre-requisites should be strengthened to specify that laboratories should comply with the *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food*, CAC-GL 27-1997.

Procedures

We recommend that the procedures should apply to both official and officially-recognised laboratories. An official laboratory would be a laboratory administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both. An officially-recognised laboratory would be a laboratory that has been formally approved or recognised by a government agency having jurisdiction.

Point 1

These considerations are based on perceived credibility rather than actual performance.

We agree that lower precedence should be given to methods validated only in a single laboratory.

The procedure should not imply that the dispute can or will occur because laboratories use different methods - this is not correct, it is the execution of a method that is important. After all, all methods for the same parameter are supposed to measure the same thing. For instance, a laboratory using a reference should not be automatically believed over a laboratory using another method, regardless of the laboratory performance, when both methods have been validated and both laboratories have satisfactory QA procedures. Further, in New Zealand's experience it is quite common for two laboratories to disagree markedly, when both are using the same method (and both have satisfactory QA procedures).

Point 2

This procedure could lead to either or both laboratories attempting to resolve the dispute using a test method for which they have no experience or no expertise.

There is a technical issue for how results (or maybe outcomes) are to be compared, especially since it is highly likely that because of 'test errors' the two laboratories will not get exactly the same test result. One needs some concept of 'allowable difference', although this might still present a problem if one outcome says the product passes, and the other than the product fails.

The procedure could usefully mention of the possibility of analysing reference samples in conjunction with the samples under dispute.

Point 3

We foresee some issues with the engagement of a third laboratory. This has the potential to create another opinion on the status of the product without providing any additional evidence to be able to say which party is making the correct decision.