SAMPLING: NEW APPROACHES IN VIEW OF CODEX STANDARDS

HOW DOES THIS MEET CODEX REQUIREMENTS? FUTURE OF SAMPLING?

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We have heard about:

- Need for sampling

- Significance of Sampling – link between sampling and Codex specification

- Difficulty of understanding sampling from a Codex Committee delegate point of view

- Codex General Principles on the Establishment of Codex Sampling Plans

- Acceptance sampling

- Uncertainty from Sampling – showing just how large it is, particularly with respect to uncertainty from analysis.

We have heard about:

- Interpretation of legislation taking sampling into account

- NMKL project

- New Zealand project work

Not yet heard about:

- Auto-control

- CCMAS undertaking rather more in this area than at present?

- Pragmatic sampling (i.e. define uncertainty from sampling as zero.)

What do we do now?

Nothing?

Stop Codex Committees making a vague reference to the Sampling Guidelines GL 50

Leave the section effectively missing in the Codex Standards?

If there were ever a dispute, would that cause problems?

The amount of time and effort spent on analysis issues (including endorsement) is disproportionate compared to the amount of time spent on sampling issues. But sampling disagreements would have a much larger effect?

Auto-Control

Auto-control is a system based on the official use of results of self-monitoring obtained by a production facility. Provided that the validity of these factory results can be verified they could replace the official control laboratory results to decide if the product meets quality specifications.

Problems with present system

Difficult to improve present system on cost basis – but are we losing much available data. Some sectors have looked the possibility of using manufacturer's continuous control data.

Within a single country that is possible – but for cross border issues it becomes much more difficult.

WHAT ARE THE BENEFITS OF AUTO-CONTROL TO THE MANUFACTURER?

There are a number of benefits to the manufacturer if auto-control is formally introduced; these are outlined below:

Auto-control allows much better overall control of product quality, by allowing access to results from a manufacturer's much higher level of in house sampling and analysis than is the case with official spot check sampling.

Does not add significantly to the manufacturer's in-house control costs, assuming they have a sound knowledge of the statistical procedures involved and have suitably trained staff.

Gives immediate assurance of product quality to both the manufacturer and customer.

Allows decisions to be made immediately by the manufacturer without an unknown delay awaiting official results.

Allows the manufacturer to plan ahead regarding marketing of the product, without a delay of several weeks, as is the case with official sampling of every lot.

Allows a small fixed level of results outside the specifications without rejection of the whole or part consignment.

Prevents potentially disproportionate rejection of large tonnages of product (i.e. the complete batch) with official control procedures when unsatisfactory sample results are found.

Prevents disputes over differences between official analytical results and in-house results as there is a continuous assessment of the product.

WHAT ARE THE ADVANTAGES OF AUTO-CONTROL TO THE CONTROL AUTHORITIES?

Overall consignment quality is based on a much more scientific and statistically sound basis than in the existing system, which relies on an assumption of failure between a previous satisfactory sample and the following satisfactory sample, even though only one random sample may have been out of specification by a small margin.

Prevents disputes over differences between official analytical results and in house results.

Limited financial savings for the Control Authorities would be gained once the system of sampling/testing of every lot was replaced by an agreed percentage spot check. This is variable depending on the number and frequency of tests required for the more complex tests.

IS THERE A RISK OF DATA MANIPULATION?

In theory there is that possibility, but for each lot produced the control results obtained must be documented and made available to the control authority on request. Production dates must be recorded and the sample must be available for inspection for a certain period of time. A control inspector may occasionally visit the factory unannounced and take a random sample of product already produced. The product is analysed in, say, a dairy laboratory together with a sample of known composition and the results are compared with the control results obtained by the dairy. In order to reassure consumers this could be a mandatory part of the system.

But fraud is an on-going issue as we have seen recently!

ARE THERE DISADVANTAGES ASSOCIATED WITH AUTO-CONTROL?

Yes. Setting up and maintaining auto-control could not be introduced without some effort from all interested parties. It is worthwhile to consider some perceived disadvantages in order that these can be taken into account when deciding whether or not to proceed with setting up an auto-control system in a factory.

Auto-control requires a formal period of official assessment of the manufacturers' procedures and in house results prior to official recognition to proceed. A detailed dossier of all sampling procedures, test methods and results must be maintained at all times. Approval could take minimally 3-6 months.

A significant increase in official monitoring of manufacturers, weekly results will be necessary to monitor trends and make comparisons with official results, i.e. an increased administrative burden.

Authority to practice auto-control can be withdrawn at short notice if a significant divergence between official and in house test results is found. Re-approval may not be permitted within 6 months.

Auto-control is only practical for the test parameters for which the manufacturer's laboratory has the capability to carry out accurate testing.

There are many complex tests required within Intervention schemes for which the manufacturer is not equipped or cannot provide the analytical expertise to produce results.

Auto-control, at best can only provide limited assurance of the overall product quality for the simpler tests. The more complex parameters still require to be tested by an Official laboratory. Therefore savings to the control authorities may be minimal.

There is a risk of sample result manipulation by unscrupulous in-house laboratories, which requires an increased level of control by Official Authorities. An increased level of random spot check visits to the manufacturing site would be necessary with witnessing of testing on site.

A sound knowledge of procedures is required to allow both the manufacturer and the Authorities to assess and compare results.

Small scale manufacturers may not be interested in taking up the option of Auto Control as their in house laboratory testing capabilities may not be comparable with official testing. Therefore any advantages to them or the official authorities are eliminated.

Manufacturers must retain product samples for a period, for subsequent retesting by official authorities to ensure validity and accuracy of original testing.
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A level of official control (sampling and analyses) will still be required. This should be based on a risk based approach. Although this may only be around 5% of batches it will incur costs to the control authority.

WHAT HAS HAPPENED SINCE THE LAST SESSION – DRAFT OF A DISCUSSION PAPER ON SAMPLING IN CODEX STANDARDS

Sets out:

Background

Introduction and General Background: Strategies for Ensuring Appropriate Quality Of Sampling

Assumption of a representative sample (ARS).
Estimation of uncertainty from sampling (UfS)
Acceptance Sampling (AcS)
Responsibility for sampling: regulator, or producer (e.g. by 'auto control')
Conclusions - comparison of approaches

Introduction and General Background from a Codex Perspective

Principles for the Establishment or Selection Of Codex Sampling Procedures

Instructions on Codex Sampling Procedures Based On Acceptance Sampling Procedures

Guidance on Uncertainty from Sampling Approach

Auto-Control of the Production Process

Assume Representative Sample Is Taken From a Lot

Discussion and Recommendations

Annex A: Principles for the Establishment or Selection Of Codex Sampling Procedures

Annex B: Explanation of and Guidance on Uncertainty from Sampling Approach

Annex C: Auto-Control of the Production Process

Annex D: Instructions on Codex Sampling Procedures Based On Acceptance Sampling Procedures

DISCUSSION AND RECOMMENDATIONS IN CCMAS DISCUSSION PAPER

The procedures which may be utilised for sampling are described in this paper, together with their strengths and weaknesses. In some instances the possible approaches are too complex to be readily understood by Codex Committees or do not comply with the current Codex General Principle of Sampling.

The following points have been made that CCMAS might want to consider.

In particular:

To recognise that different sampling plans when applied to the same lot may result in different assessments of the lot with respect to a Codex specification. In that way sampling is similar in effect as Type I, empirical, method of analysis, i.e. if a sampling plan is not specified then the application of different sampling plans by different operators to the same lot may result in different decisions with respect to compliance of the lot with the specification. In addition, the application of the same sampling plan by different operators to the same lot may also result in different decisions with respect to compliance.

To recognise that sampling is complex and inherently variable when considering lots. As a result many Codex Committees do not specify a defined sampling plan in many (most?) of their Standards.

To recognise that an estimate of the "variability" can now be quantified and expressed as a (measurement) uncertainty from sampling in the same way as measurement uncertainty can be quantified and expressed.

Whether to review and revise the "Principles for the Establishment or Selection of Codex Sampling Procedures" to permit procedures besides acceptance sampling procedures to be used.

Whether to review and revise the "Principles for the Establishment or Selection of Codex Sampling Procedures" to determine if their current scope is appropriate. In particular whether Codex is currently directly concerned with "net contents" and, if not, whether to delete this section from the Principles.

Whether to discourage Codex Committees from only making reference to the Codex General Guidelines on Sampling (CAC/GL 50-2004) in their Standards as the defined sampling plan, and not making reference to the specific table(s) for the sampling plan(s).

To discuss means of ensuring the Principles for the Establishment or Selection of Codex Sampling Procedures are implemented appropriately when Codex Committees define sampling plans in their Standards.

Whether to encourage Codex Committees which do not appreciate the application of CAC/GL 50-2004 to request a working group of CCMAS to undertake the development of the appropriate sampling plan. Such Codex Committees, however, would retain responsibility for specifying the criteria that the plan is required to meet but may have to provide information to CCMAS on, for instance, desired levels of consumers' risk, producers' risk, AQL and LQ; or alternatively Codex committees should approve sampling plans developed by CCMAS.

To decide whether any estimated uncertainty from sampling should be taken into account when assessing compliance in the same way as uncertainty from analysis is taken into account.

To note that following the publication of the EURACHEM/EUROLAB/CITAC/Nordtest/AMC Guide on the "Estimation of Measurement Uncertainty Arising from Sampling" and the Nordtest handbook "Uncertainty from sampling- a Nordtest handbook for sampling planners on sampling quality assurance and uncertainty estimation" the issue of uncertainty and sampling cannot be ignored and so decide whether CCMAS should develop recommendations in the area in the same way that it already has for [Analytical] Measurement Uncertainty.

To consider whether auto-control procedures can be readily applied in the Codex situation – as opposed to the easily defined (and confined) control situation within a single country.

To consider whether simple "pragmatic" sampling plans should be used within Codex, whether scientifically correct or not. In many instances this is what happens in practice.

CRITICAL POINTS:

Examples of sampling plans in Codex. Lack of examples in the Codex sampling area. Need to develop these?

Discussion Document. Should this be up-dated and made available in the Codex system or outside of system (e.g. as RSC publications)?

Codex Committees have problems with the sampling area. Should CCMAS carry out the work for them or need to inform the other Committees?

How detailed should the final plan be? Is reference to the tables in GL 50 sufficient? Who should specify AQL, sample sizes etc? Do we need additional guidance in CCMAS to interpret the Guidelines?

CRITICAL POINTS:

Balance of work in CCMAS. Much easier to discuss analysis aspects, but sampling is in general more significant. How is this to be addressed?