CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 7 **CX/MAS 14/35/7**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Thirty-fifth Session
Budapest, Hungary, 3 - 7 March 2014

DISCUSSION PAPER ON SAMPLING IN CODEX STANDARDS

(Prepared by eWG chaired by the Inter-Agency Meeting)

INTRODUCTION

It was agreed at the 34th Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS) that the Inter-Agency Meeting (IAM) would prepare a discussion paper for the 35th Session on sampling issues, this following a brief discussion at the 34th Session. This paper is attached.

Besides members of the IAM, participants from Australia, Brazil, Canada, Ecuador, France, Hungary, Jamaica, Japan, JRC-IRMM (EU), Mauritius, New Zealand, Norway, Serbia, UK, Uruguay and USA asked to be involved as that paper was prepared.

As would be anticipated there were conflicting views and opinions, particularly as representatives from one country dislike the "Uncertainty of Sampling" approach, as described in the Guide "Measurement uncertainty arising from sampling" produced internationally between EURACHEM, EUROLAB, Nordtest and the UK RSC Analytical Methods Committee.

RECOMMENDATIONS FROM IAM PAPER

For convenience the considerations and recommendations given in the discussion IAM paper are reproduced below. This Session of CCMAS may wish to consider if/how it should re-act to these.

1. 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.

2. 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.

3. 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.

4. 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.

5. 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 Principle.

6. 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).

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

IAM PAPER ON "SAMPLING IN CODEX STANDARDS – HOW IT SHOULD BE TREATED"

A DISCUSSION DOCUMENT

CONTENTS

BACKGROUND

In the Report of the 34th Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS) it states:

"79. The Observer from ICUMSA recalled that the 33rd session of the Committee had agreed to ask the IAM to provide a short discussion paper on sampling issues for consideration at the next session, and introduced CRD 8, recalling the evolution of sampling in the framework of Codex and earlier discussions on measurement and sampling uncertainty. The Observer noted that in some cases Codex Committees simply referred to the General Guidelines on Sampling instead of selecting specific sampling plans and that the current guidance to Codex committees and to governments needed to be reviewed. For this purpose the discussion paper considered the following possibilities:

a. Acceptance Sampling

The present approach defined by the Codex Sampling Principles. It does require an understanding by the Codex Committees of the variability that is inherent with acceptance sampling plans, and in particular the relatively high probability of accepting a lot with unsatisfactory material in it. This is not currently understood by many Codex Committees.

b. The Estimation of the total uncertainty from both analysis and sampling

Procedures for the quantification of the total uncertainty in the measurement process, including that from both analysis and sampling will be considered. Whether such uncertainty could be reduced to an "acceptable" level, normally by taking more sample increments (units) or reducing the variability within the lot being sampled will be assessed.

c. Representative/Pragmatic Sampling

Whether to ignore all aspects of sampling uncertainty and define a practical plan on little scientific basis.

d. Auto-Control

A radically different approach, i.e. verifying the results obtained from continuous food production. This approach, called here "auto-control", has been considered in international Working Groups.

80. The Observer proposed to address this issue with the development of a discussion paper for consideration at the next session, to review existing and possible new approaches to the establishment of sampling plans within Codex.

81. Several delegations pointed out that the document had been made available only at the session and therefore discussion should be postponed to the next session. Several other delegations stressed the importance of addressing sampling issues, especially uncertainty, and noted that CRD 8 provided a good basis for further discussion. The Committee discussed whether to establish an electronic working group and its possible terms of reference, as presented in CRD 19. Some delegations expressed the view that the mandate of the working group and purpose of the discussion paper should be more clearly defined before proceeding with further work.

82. The Observer from AOCS, speaking as Secretariat of the IAM, recalled that the last session of the Committee had agreed that the IAM would develop a discussion paper and proposed to follow this process again. The Committee welcomed this proposal and agreed that the IAM would develop a paper on sampling and would invite interested delegations to participate in the process. The Committee noted that in practice, all members and observers would be informed of the initiative of the IAM through the Codex lists of distribution and they could provide their contribution directly to the IAM (through AOCS). The Committee also welcomed the offer of New Zealand to make a web based platform available to facilitate the development of the document in a transparent and interactive manner. The result would be a paper on sampling issues to be presented by the IAM for consideration at the next session of the Committee."

This document attempts to further develop some of the issues and gives a brief introduction to the various approaches to sampling which are currently discussed at an international level.

It should be appreciated that the there are widely differencing views from sampling experts about some of the information given – some very supportive, others fundamentally disagreeing with the documents/guides that have been published by international groups.

This discussion document does not attempt to recommend any one of the different approaches, but does give information on what they may be.

It should be noted that elements of the document will be abstracted and published as a series of RSC Analytical Methods Committee Technical Briefs. Information of these Briefs, which are freely downloadable may be obtained from the AMC Website[1].

INTRODUCTION AND GENERAL BACKGROUND: STRATEGIES FOR ENSURING APPROPRIATE QUALITY OF SAMPLING

The quality of measurements of analyte concentration in materials such as food, water, air and soil, is limited by the quality of the primary sampling process, as much as by that of the chemical analysis. Whist a consensus has been reached on how to ensure the quality of chemical analysis, there is still disagreement on how to ensure the appropriate quality of sampling. Three options to ensuring sampling quality (ARS, UfS, AcS) will be briefly described, and their strengths and weaknesses assessed for their applicability to the sampling of various materials, particularly for regulatory purposes. The related issue of whether the sampling and measurement activity should be the responsibility of the regulator, or the material producer (e.g. as part of 'auto control') will also be discussed.

Assumption of a representative sample (ARS).

The Theory of Sampling proposes that the correct application of a correctly designed sampling protocol automatically produces a representative sample of a batch of material[2]. The uncertainty in the resultant measurement of the concentration of a component in the material (e.g. aflatoxin in nuts) therefore arises only from the final chemical analysis. Ensuring the quality of the sampling focuses initially on using knowledge of the properties of the material and the sampling devices to calculate and select parameters for the correct protocol (e.g. the number of increments, total sample mass and position of sampling). Secondly it relies on sufficient training of the sampling personnel (the sampler) to apply the protocol correctly.

Strengths:-

1. Easy to implement, once the correct protocol has been devised.
2. Mathematical modelling can be applied to calculate the protocol parameters if all the properties of the material are known in advance.

Weaknesses:-

1. Underestimates the overall uncertainty of the measurement (excludes contribution from sampling), which will affect the reliability of decisions on batch acceptance/rejection.

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1 See - http://www.rsc.org/Membership/Networking/InterestGroups/Analytical/AMC/TechnicalBriefs.asp

2 Gy P M (1979) *Sampling of Particulate Materials – Theory and Practice*. Elsevier, Amsterdam, 431pp.

2. Does not give the information on sampling variability (and hence larger measurement uncertainty) to the decision maker.
3. No way of checking on the quality of the actual implementation of the sampling protocol in routine operation.
4. Hard to devise correct protocol for heterogeneous material sampled *in situ* (e.g. un-mixed nuts in a container, or contaminated land).
5. Expense of gathering, and assumption of consistency, of all the information required for the design of the correct protocol (e.g. dimensions and distributions of particles).

Estimation of uncertainty from sampling (UfS)

Approaches, such as the empirical Duplicate Method, can be used to estimate the contribution from sampling and sample preparation to the uncertainty in the measurement of concentration of a component in a sampling target (e.g. aflatoxin in batch of nuts)[3],[4]. The heterogeneity of the analyte within the material, and the inevitable ambiguity in whatever sampling protocol is selected, will automatically be included in this uncertainty estimate. A validation of the sampling protocol requires the application of the Duplicate Method to at least eight typical sampling targets. The continuing applicability of the validation result is monitored using on-going quality control of the sampling and analytical processes[2].

Strengths:-

1. Gives a realistic estimate of the measurement uncertainty, which will make decisions on batch acceptance/rejection more reliable.
2. Use of empirical data from actual sampling of eight real batches in validation makes estimates of protocol performance more reliable than those based upon model predictions (e.g. ARS)
3. Applicable to any measurement/sampling protocol, even if sample mass would not be considered 'correct' for representative sampling (i.e. ARS).
4. Enables the fitness-for-purpose of the measurements (& sampling) to be judged in terms of minimizing the overall costs of both measurement and incorrect regulatory decisions.
5. Inclusion of sampling quality control monitors on-going performance of samplers in routine application of the protocol, not just at validation.

Weaknesses:

1. Expense of additional duplicate samples in validation exercise and on-going quality control.
2. Methodology for including uncertainty from sampling in decision-making process not yet agreed.

Acceptance Sampling (AcS)

Like the UfS approach, acceptance sampling also uses the empirical evaluation of sources of variability from all stages in the measurement process on a range of batches of the target material[5], [6]. The difference arises on how these estimates are treated, with only analytical variability considered as part of the measurement uncertainty. The risks to the producer (or seller) and to the consumer (buyer) are calculated and then the acceptance quality level (AQL) and the sampling protocol parameters (e.g. sample and sub-sample masses) selected to balance the two risks, using an operating characteristic curve. Once the final sampling protocol has been designed, it is assumed that it is applied correctly to subsequent batches, as for ARS.

Strengths (in addition to strength 1 of ARS)

1. Recognises that producers and consumers both have risks of incorrect decisions and that they need to be balanced.
2. Makes empirical estimates of variability arising from sampling, sample preparation and chemical analysis, and uses them to adjust the effective threshold (e.g. as AQL).

Weakness (in addition to weakness 1, 2, 3 & 4 of ARS):

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[3] Eurachem/EUROLAB/ CITAC/Nordtest/AMC Guide: *Measurement uncertainty arising from sampling: a guide to methods and approaches* M H Ramsey and S L R Ellison (eds.) *Eurachem* (2007).

[4] Analytical Methods Technical Brief on UfS currently being drafted

[5] Analytical Methods Technical Brief on acceptance sampling currently being drafted

[6] Whitaker TB (2006) Food Additives and Contamination, Part A, 23, 50-61

1. Does not include potential financial losses that may arise from decision errors (caused by uncertainty) in calculation of final sampling protocol.
2. Gives rise to a high probability of accepting defective items, especially for small batches, that is not appreciated by some regulators.

Responsibility for sampling: regulator, or producer (e.g. by 'auto control')

Auto control uses the measurements from routine sampling and analyses, made as part of product control, to enable regulators to decide if the sampling and measurement methods are of sufficient quality[7]. This question is independent of which of the three options discussed above is used to design the sampling protocol. It is related to whether the regulator should be responsible for protecting the interests of the consumer, or whether the regulator can delegate that responsibility to the producer of the material (e.g. nuts that might contain aflatoxins). A free-market approach might suggest that the producer has a financial motivation to ensure that consumers are not adversely affected by their product. A consumer-protection approach might argue that short-term profit might be considered more important by the producer than a long-term health effect (e.g. cancer from aflatoxins) the causation of which is hard to prove after say 20 years.

Strengths:

1. Reduces cost to regulators (and therefore tax-payers) of sampling and measurement, as measurements are already being taken for process control.
2. Does uses the equivalent of the UfS information, in moving the effective threshold value (e.g. to AQL)
3. Well-controlled manufacturing processes will provide much greater numbers of measurements than could be made realistically by a regulator, and therefore a better chance of detecting an unacceptable product.

Weaknesses:

1. Is not applicable to all materials (e.g. containers of bulk materials, such as nuts, arriving from counties where auto control is not used)
2. It can be difficult to ensure the long-term rigour of the auto-control results with changes of production methods and management personnel.

Conclusions - comparison of approaches

1. Only in the UfS approach does the information from the validation step (e.g. on the portion of the measurement uncertainty from sampling and sample preparation) get reported to the user of the measurement results. (e.g. 15 ± 10 ng g^{-1}, rather than just the analytical portion 15 ± 1 ng g^{-1})
2. The differences in terminology of the three approaches reflect deeper distinctions. For example, the 'variability' due to sampling in AcS produces 'uncertainty' in the measurement (of concentration) that is not reported to the user (i.e. producer, consumer or regulator)
3. The more realistic estimate of measurement uncertainty given by the UfS approach is essential to making reliable decisions and classifications on the acceptability of material for its intended purpose (e.g. safety of food for consumption). The methodology for using this uncertainty information in enforcement decisions is not yet agreed internationally, for example in deciding the acceptable levels of false positive (producer's or seller's risk) and false negative (consumer's or buyer's risk) classifications. However, the UfS approach will enable this methodology to be applied not just at the validation stage, but also in routine operation.
4. Both ARS and AcS consider sampling variability in the design of the initial sampling protocol, but don't consider or express it as part of the measurement process. This has the advantage of apparent simplicity, but misleads the decision maker on the reliability of the classification decision. However, the AcS approach uses the equivalent of the UfS information, in moving the effective threshold value (e.g. to AQL)
5. All of the approaches rely on sufficient training and monitoring of the samplers, but UfS recommends the use of sampling quality control (and in some cases sampling proficiency tests) to assess and improve their performance.
6. Approaches such as 'auto control' may be a practicable option for a small proportion of cases, but it is not widely applicable, and would lead to reliance on the self-monitoring by producers that would (may) not be impartial.

[7] Analytical Methods Technical Brief on auto-control currently being drafted

INTRODUCTION AND GENERAL BACKGROUND FROM A CODEX PERSPECTIVE

Codex sampling plans are designed to ensure that fair and valid procedures are used when food is being tested for compliance with a particular Codex commodity standard. The sampling procedures are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in the light of the relevant provision(s) of the applicable Codex standard.

Codex Committees, when including provisions (characteristics) in a Standard, relate the numerical value of the characteristic, the associated method of sampling and method of analysis to each other. The Codex Principles for Analysis and Sampling (Section II, Codex Alimentarius Commission, Procedural Manual, Twenty-First Edition) are intended to ensure that this will be done when selecting Codex methods of sampling and analysis for inclusion in Codex Standards.

The relationship between the value of a characteristic in a Codex Commodity Standard and the method of analysis to estimate that value can be readily appreciated, but the link between the value of the characteristic and the method of sampling is less well understood. In order to assist in the appreciation of the relationship between Standard and method of sampling the Codex Committee on Methods Analysis and Sampling (CCMAS) has elaborated "General Principles for the Establishment or Section of Codex Sampling Procedures". These General Principles have now been adopted by the Codex Alimentarius Commission; they are given in Appendix I of this discussion paper for easy reference. They are very acceptance sampling orientated.

It will be seen that there are many similarities between the two aspects (i.e. sampling and analysis) of the General Principles; in particular they are both trying to define the relationships between the value of a characteristic in a Standard and the methods (of analysis or of sampling) used to verify compliance with the value.

Before any characteristic in any Codex Standard is elaborated it must be appreciated that the value of the characteristic in that Codex Standard is dependent on the procedures used to ascertain that value of the characteristic.

In particular, the estimate of the value may be dependent upon the method of analysis used, but is always dependent on the type of sampling plan and the lot acceptance procedure used. It is, therefore, necessary that when characteristics within a Standard are elaborated, the sampling and lot acceptance procedures to be prescribed to verify those characteristics are also considered at the same time, so that the characteristics are related to the procedures.

This may be best illustrated by reference to the 'types' of methods of analysis which have been adopted by the Codex Alimentarius Commission[8]. It is stated that Type I methods 'define' the value of the characteristics in the Standard and so only a single Type I method can be prescribed in such cases. In addition it is a mandatory requirement to accept the Type I Codex method if the Standard itself is to be accepted – i.e. the separation of the value of the characteristic and the relevant Type I method is, in effect, meaningless. It has, therefore, been agreed by the Codex Committees on Methods of Analysis and Sampling and on General Principles that non-acceptance of the Codex defining methods, or acceptance of Codex Standards with substantial deviations in the Codex defining method, should be taken to mean acceptance of the Codex Standard with a specified deviation.

Types II and III Codex methods determine the content of a defined chemical entity and these methods may be used interchangeably depending upon the particular situation except that Type II Codex methods are intended to be obligatory in cases of disputes concerning the results of analysis. This has been further extended by the introduction of the method criteria for Type II/III methods.

In order to aid Codex Committees appreciate the relationship between characteristic and sampling Codex has developed Guidelines on Sampling (see CAC/GL 50-2004) which are intended to ensure that the General principles are fully understood and correctly applied in the selection of Codex sampling procedures. It was also intended that these Guidelines should be complete in themselves without the need to make cross reference to any other document except that the ISO guidelines on the layout of method of sampling from a lot should also be considered when drawing up a sampling procedure.

In addition, note should be taken of any implications of packaging considerations and how they might affect the sampling procedures. Where such effects have been specifically considered, they should be noted in the sampling plan proposed**.**

However, these Guidelines have proved to be rather complex from the Codex Committee perspective as such Committees often just refer to the Guidelines without selecting from them when they draw up sampling plans. They are frequently considered to be too complex and not readily appreciated by the “lay” user.

It is because of these considerations that IAM members offered to develop discussion documents with the help of volunteers from participants at the last CCMAS Session.

This paper aims to explain the various approaches to sampling that may be undertaken within Codex.

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[8] See Codex Procedural Manual

It is formed from a number of Annexes, these being:

A: Principles for the Establishment or Selection of Codex Sampling Procedures

B: Explanation of and Guidance on Uncertainty from Sampling Approach

C: Auto-Control of the Production Process

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

They are discussed below and recommendations given.

PRINCIPLES FOR THE ESTABLISHMENT OR SELECTION OF CODEX SAMPLING PROCEDURES

Introduction

The Codex Principles for the Establishment or Selection of Codex Sampling Procedures were developed and adopted in the 1980s; there have only been minor changes since their first adoption. They are given in Annex A to this paper. They lay down the presumption on which sampling procedures are to be established; most notably that such procedures are to be based on acceptance sampling. This requirement is now rather restrictive and there is merit in re-visiting the Principles with a view to see if they are still as applicable as they first were. Clearly new approaches to sampling have been developed and Codex Committees may wish to propose them.

Their scope should also be considered, most notably whether they should apply to "net contents".

Recommendation

That the Codex Principles for the Establishment or Selection of Codex Sampling Procedures be re-considered with respect to their applicability and scope.

INSTRUCTIONS ON CODEX SAMPLING PROCEDURES BASED ON ACCEPTANCE SAMPLING PROCEDURES

Introduction

Acceptance sampling procedures have been established for many years; they were first commonly used in WW2 in the 1940s. The Instructions given in Annex D were first developed in 1988 and are written in simple terms. They were then extended and adopted as Codex Guidelines in 2004.

Codex has had various attempts at explaining their use, but such usage tends to become rather complex and as a result Codex Committees, when drawing up sampling plans, simply refer to the Guidelines without selecting a sampling plan, or possibly understanding the significance of the plans.

The plans do require selection and analysis of a set of units taken from a defined batch. The plans are empirical in that the final result (or compliance decision) is very dependent on the number of units taken, the Acceptable Quality Level which is prescribed etc.

The information given in Annex D diagrammatically explains how such plans are developed, and the associated numeric factors. Rather than simply developing operating characteristic (OC) curves, the risks are given in numeric form. As a real example sample sizes and acceptability at different AQL levels and percentage of rejectable quality items in lots having 95%, 50% and 10% chance of being accepted for variables acceptance sampling plans with unknown standard deviation are abstracted from Table 4 of Annex D.

Sample Size (n)	**AQL of Plan (%)**	**Percentage of Defectives in a lot which may be Accepted**		
		95%	**50%**	**10%**
		of the time		
3	10.0	6.0	31	62
4	10.0	6.9	29	56
5	10.0	7.1	26	50
7	10.0	7.5	24	43
10	10.0	7.5	24	43
15	10.0	8.4	19	32
20	10.0	8.9	18	29
25	10.0	9.3	18	27
35	10.0	9.7	17	24
50	10.0	10	16	22
75	10.0	10	15	20
100	10.0	11	15	19
150	10.0	11	14	17
200	10.0	11	14	17

This table demonstrates that using an AQL of 10% the percentage defectives in a lot which will be accepted 95% of the time remains fairly constant no matter the sample size. However, the percentage of defectives which would be accepted 10% of the time increases dramatically as the number of units taken for analysis decreases. Unfortunately because there is always a pressure to reduce the amount of sampling and associated analysis, the number of units taken if often unreasonably small and it is only by looking at the 50% and 10% columns that the risks are clearly and easily identified and appreciated.

Recommendation

That acceptance plans are only developed for specific system by those who fully appreciate their significance and associated difficulties and that the consequence of reducing the number of units taken from a lot area clearly appreciated.

GUIDANCE ON UNCERTAINTY FROM SAMPLING APPROACH

Introduction

"Methods of sampling" have had a long and troubled history within Codex. The majority of the work described within Codex is based on the use of acceptance sampling plans, and is frequently very complex. As a result Codex Commodity Committees frequently refer to the use of CAC/GL 50-2004 (the Codex General Guidelines on Sampling)

but then do not progress further than that. They do not choose from the options given in 50-2004 as should happen.

With the publication of the EURACHEM/EUROLAB/CITAC/Nordtest *Guide on the Estimation of Measurement Uncertainty Arising from Sampling;* and Nordtest handbook for sampling planners on sampling quality assurance and uncertainty estimation *Uncertainty from sampling*, this paper considers that it would be unwise to ignore this area of measurement uncertainty. To do so will result in the same issues and confusion that have already arisen when analytical measurement uncertainty has been considered.

Discussion

As stated above sampling has long been recognised as part of the measurement process, when the measurand (or true value to be determined) is defined in terms of the sampling target (e.g., a batch/lot of material) rather than in terms of the laboratory sample. Several methods have been proposed to estimate measurement uncertainty arising from all steps in the measurement process, including the primary sampling. Once an estimate of the uncertainty has been made, it is necessary to address whether that level of uncertainty is acceptable in order to decide whether the measurements are fit for the purpose for which they are intended. (One approach to this question, not discussed in this paper, is to designate this optimal value of uncertainty, as the point that minimises the overall financial loss to the user of the measurements).

However, for Codex purposes it is possible to pre-define a fit-for-purpose value for the measurement uncertainty, including both the "analytical" and "sampling", such that any sampling plan which is developed will meet that criterion. Clearly this then becomes an iterative process.

Thus as a result of the international activities it is critical for CCMAS to recognises that a decision has to be taken as to whether sampling uncertainty should be taken into account when assessing compliance, or whether it wishes to take the non-scientific/simplistic route of defining sampling uncertainty as being zero. In addition it could suggest that Codex Commodity Committees recommend the maximum uncertainty that is fit-for-purpose.

Recommendations

It is recommended that Codex:

- Notes the publication of the EURACHEM/EUROLAB/CITAC/Nordtest Guide on the "Estimation of Measurement Uncertainty Arising from Sampling" and the Nordtest handbook.
- Discusses the issue of uncertainty and sampling and decides whether it should develop recommendations in the area in the same way that it already has for [Analytical] Measurement Uncertainty.
- Discusses whether sampling uncertainty should be taken into account when a lot is assessed for compliance with a Codex specification.
- Considers whether it should prepare Guidance for Codex Committee Committees on uncertainty from sampling.

AUTO-CONTROL OF THE PRODUCTION PROCESS

The principles of auto-control, its advantages and disadvantages, are explained in Annex C, which originated from an EU Expert Chemists Group. It was originally targeted towards the milk sector but may be extended generally.

Auto-control is a self-monitoring system for collecting the information required to check that products meet quality requirements. It makes use of the data that many manufacturers already have available as a result of their own routine in-house quality monitoring. Auto-control is not intended to replace entirely the existing system, which involves analysis of samples by an official control laboratory. It would not be introduced as mandatory procedure.

The approach may be considered the most "cost effective" as it utilises data which has to be produced in an on-going system where the product is already controlled by an analytical procedure.

ASSUME REPRESENTATIVE SAMPLE IS TAKEN FROM A LOT

The simplest sampling procedure is to take a defined number of units from a lot, combine them into a single sample and then analyse that sample. If the result complies with the specification, after taking analytical measurement uncertainty into account, then the lot is deemed to be compliant.

The approach effectively assumes no uncertainty from sampling (or at least ignores any uncertainty!). In many respects that has been the "traditional" approach but the least scientific!

DISCUSSION and RECOMMENDATIONS TO THE 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.

It is therefore suggested and recommended that Codex considers the following:

1. 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.
2. 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.
3. 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.
4. 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.
5. 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 Principle.
6. 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).
7. 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.
8. 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.
9. 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.
10. 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.
11. 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.
12. 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.

ANNEX A: PRINCIPLES FOR THE ESTABLISHMENT OR SELECTION OF CODEX SAMPLING PROCEDURES

Purpose of Codex Methods of Sampling

Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard. The sampling methods are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.

Methods of Sampling

Types of Sampling Plans and Procedures

(a) Sampling Plans for Commodity Defects:

Such plans are normally applied to visual defects (e.g. loss of colour, misgrading for size, etc.) and extraneous matter. They are normally attributes plans, and plans such as those included in Section 3.1 and 4.2 of the *General Guidelines on Sampling (CAC/GL 50-2004)* (hereinafter referred to as "General Guidelines") may be applied.

(b) Sampling Plans for Net Contents:

Such plans are those which apply to pre-packaged foods generally and are intended to serve to check compliance of lots or consignments with provisions for net contents. Plans such as those included in Section 3.3 and 4.4 of the General Guidelines may be applied.

(c) Sampling Plans for Compositional Criteria:

Such plans are normally applied to analytically determined compositional criteria (e.g., loss on drying in white sugar, etc.). They are predominantly based on variable procedures with unknown standard deviation. Plans such as those included in Section 4.3 of the General Guidelines may be applied.

(d) Specific Sampling Plans for Health-related Properties:

Such plans are normally applied to heterogeneous conditions, e.g. in the assessment of microbiological spoilage, microbial by-products or sporadically occurring chemical contaminants.

General Instructions for the Selection of Methods of Sampling

(a) Sampling methods described in the General Guidelines or official methods of sampling elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such official methods may bewritten using the General Guidelines when attracted to Codex standards.

(b) When selecting appropriate sampling plans, Table 1 in the General Guidelines may be utilized.

(c) The appropriate Codex Commodity Committee should indicate, before it elaborates any sampling plan, or before any plan is endorsed by the Codex Committee on Methods of Analysis and Sampling, the following:

(i) the basis on which the criteria in the Codex Commodity standards have been drawn up (e.g. whether on the basis that every item in a lot, or a specified high proportion, shall comply with the provision in the standard or whether the average of a set of samples extracted from a lot must comply and, if so, whether a minimum or maximum tolerance, as appropriate, is to be given);

(ii) whether there is to be any differentiation in the relative importance of the criteria in the standards and, if so, what is the appropriate statistical parameter each criterion should attract, and hence, the basis for judgement when a lot is in conformity with a standard.

(d) Instructions on the procedure for the taking of samples should indicate the following:

(i) the measures necessary in order to ensure that the sample taken is representative of the consignment or of the lot;

(ii) the size and the number of individual items forming the sample taken from the lot or consignment;

(iii) the administrative measures for taking and handling the sample.

(e) The sampling protocol may include the following information:

(i) the statistical criteria to be used for acceptance or rejection of the lot on the basis of the sample;

(ii) the procedures to be adopted in cases of dispute.

General Considerations

(a) The Codex Committee on Methods of Analysis and Sampling should maintain closest possible relations with all interested organizations working on methods of analysis and sampling.

(b) The Codex Committee on Methods of Analysis and Sampling should organize its work in such a manner as to keep under constant review all methods of analysis and sampling published in the Codex Alimentarius.

(c) In the Codex methods of analysis, provision should be made for variations in reagent concentrations and specifications from country to country.

(d) Codex methods of analysis which have been derived from scientific journals, theses, or publications, either not readily available or available in languages other than the official languages of FAO and WHO, or which for other reasons should be printed in the Codex Alimentarius *in extenso*, should follow the standard layout for methods of analysis as adopted by the Codex Committee on Methods of Analysis and Sampling.

(e) Methods of analysis which have already been printed as official methods of analysis in other available publications and which are adopted as Codex methods need only be quoted by reference in the Codex Alimentarius.

ANNEX B: EXPLANATION OF AND GUIDANCE ON UNCERTAINTY FROM SAMPLING APPROACH

Introduction

It is widely accepted that repeat analyses of the same sample will almost always produce varying results. These variations may be due to e.g. changes in the operating conditions, and an inhomogeneous sample from which only a small test portion is taken. Persons responsible for producing, appraising and interpreting the results of chemical analyses will be familiar with terms such as reproducibility and repeatability - both are measures of this random variability. They will also be familiar with the use of 'reference materials' and terms such as 'bias' and 'recovery', which are used to check if analytical results are systematically higher or lower than they should be, when compared to a known reference value. The random variability and systematic effects in analytical results are characterised as analytical uncertainty.

Chemical analysis is usually the end part of the measurement process, following the taking of samples (sampling) and grinding, blending and treatment of samples in preparation for chemical analysis (physical preparation). The term 'measurement' (as in measurement uncertainty) encompasses the whole procedure. Each step in the measurement process will introduce variability in the final measurement result, the measurement uncertainty. The International Standards Organisation defines uncertainty of measurement as 'parameter, associated with the result of a measurement that characterises the dispersion of the values that could reasonably be attributed to the measurand' (ISO GUM 1993).

The Codex General Guidelines on Sampling (CAC/GL 50-2004) are based on the principals of acceptance sampling. They are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard. These Guidelines make the distinction between sampling error and measurement error. For the purpose of the Guidelines measurement error (caused by the measured value of the characteristic failing to accurately represent the true value of the characteristic within the sample) is analogous to analytical uncertainty. Like analytical uncertainty, sampling error (caused by the sample failing to accurately represent the population from which it was collected) has input from both systematic and random effects. The CAC Guidelines advise it is desirable that the sampling errors associated with any sampling plan, as well as measurement errors associated with analysis, should be quantified and minimised. Laboratories are required, as part of 3rd party accreditation, to participate in inter- laboratory trials, data from these and other internal quality control measures allow the estimation of analytical uncertainties. Methods for estimating sampling uncertainty have been published.

The Eurachem/EUROLAB/CITAC/Nordtest Working Group on Uncertainty from Sampling was formed in September 2003. This Working Group includes representatives from a wide range of disciplines, including those from the food sector. The Eurachem Working Group has prepared guidance for the evaluation of uncertainties in measurement arising from the process of sampling. This guidance is applicable to all chemical measurements that require the taking of a sample. It provides guidance on the assessment of the uncertainty of the measurement that is caused by the process of sampling, and any physical preparation of the sample prior to analysis, and how this can be combined with estimates of uncertainty arising from the analytical process. The guide was developed in collaboration with relevant international bodies and will be updated as experience is gained in their use.

The Guide looks firstly at the methods of estimating uncertainty and uses real case studies to exemplify each. The role of measurement uncertainty in the decision making process is also addressed, as is the assessment of fitness for purpose. The second part of this document examines whether it is a good idea to set global fitness for purpose criteria for sampling uncertainty. This document is focussed on measurement processes that result in quantitative data. Qualitative data (e.g. yes / no responses) are not addressed.

In addition Nordtest has prepared a handbook for sampling planners on sampling quality assurance and uncertainty estimation *Uncertainty from sampling,* which is based upon the EURACHEM Guide *estimation of measurement uncertainty arising from sampling,* but which is rather more "practical".

What is Measurement Uncertainty?

Even ignoring sampling uncertainty it is not always appreciated that analytical results are variable, and just how large that variability may be, particularly when low concentrations of a measurand (i.e. ppb levels) are being determined. As stated in the present Codex Measurement Uncertainty Guidelines, most quantitative analytical results take the form of "a ± 2u" or "a ± U" where "a" is the best estimate of the true value of the concentration of the measurand (the analytical result) and "u" is the standard uncertainty and "U" (equal to 2u) is the expanded uncertainty. The range "a ± 2u" represents a 95% level of confidence in which the true value would be found. The value of "U" or "2u" is the value which is normally used and reported by analysts, normally referred to as "measurement uncertainty" and may be estimated in a number of different ways.

In food analysis it is the (approximately) 95% probability (i.e. 2u) which is used to calculate the expanded uncertainty. Other sectors may specify a different probability. Thus measurement uncertainty may be regarded as the variability around the reported results which is quantified as the value "U" when considering the expanded uncertainty and within which the "true" result should lie.

The values "U" or "2u" need to take into account the total uncertainty including that contributed by the sampling uncertainty. This will probably make the value of "U" rather larger than if the sampling uncertainty is ignored.

Does Measurement Uncertainty Apply to both Sampling and Analysis?

Measurement uncertainty applies to the whole measurement process. For analysts only "analytical" measurement uncertainty has been considered but it is now increasingly being recognised that the whole system must be considered, and so "sampling" measurement uncertainty is gaining an increasing importance.

Procedures for Estimating Measurement Uncertainty

There are many procedures available for estimating the measurement uncertainty of a result.

The Codex guidelines for analytical measurement uncertainty do not recommend any particular approach, but it is important that whatever approach is used, the procedure is scientifically credible. No one approach may be said to be better than any other provided the procedure used is appropriate and credible - i.e. there is no "hierarchy" of the recognised procedures. All such procedures may be considered to be equally valid. However, the procedure that an individual laboratory uses will have to be considered appropriate by its Accreditation Agency as part of its 17025 accreditation. In general procedures are based on a component-by-component ("bottom-up") approach or on a "top-down" approach using collaborative trial data.

In Codex there is a requirement to use fully validated methods and so it is usually more cost-efficient to use data from the validation rather than using another approach (i.e. the component-by-component approach). The caveats to using such validation data are best described in the Eurachem Guide to quantifying uncertainty in analytical measurement.

However, with respect to total measurement uncertainty there are several ways of estimating sampling uncertainty but both Guides (Eurachem and Nordtest) include the "duplicate method" which has been found to be broadly applicable across the food sector.

The duplicate method – general principles

A sampling protocol (detailing, how many samples, how to sample, sample mass etc.) is a prerequisite for all food surveys, assessments etc. The duplicate method requires a second (duplicate) sample to be taken for 10% (or a minimum of 8) of the total number of sampling targets. This second 'duplicate' sample should be taken to represent the ambiguity in interpreting the protocol, what this means is perhaps better explained using the examples.

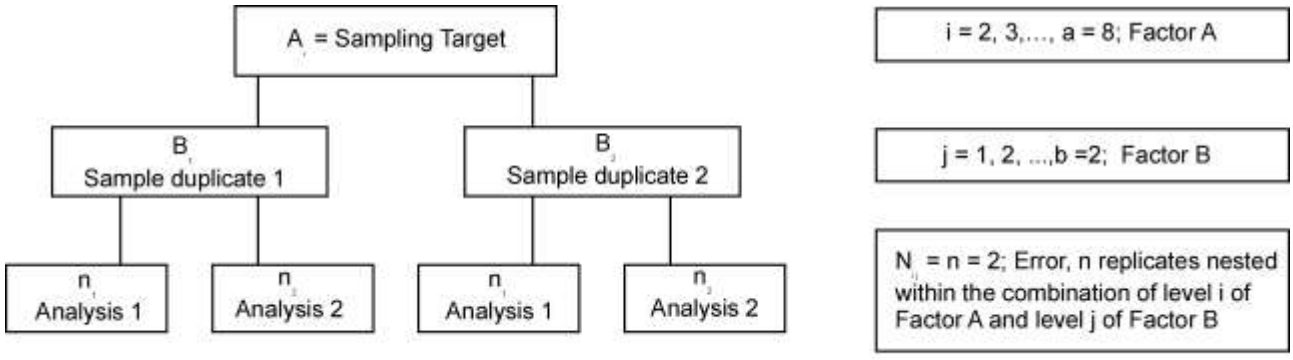
The duplicate samples are then each subject to independent physical preparation (i.e. they are not combined). Two analytical test portions are drawn from each of the duplicate 'prepared' samples.

All test portions are anonymised (so it is unclear which are duplicates) and subsequently analysed in a randomised order.

Statistical procedures are applied to the resultant data to separate out between-target variances, sampling (or within-target) variances and analytical variances.

The inclusion of certified reference materials (CRM) and /or spike samples within the analytical run will allow the systematic effects of analysis to be quantified. This is generally routine in most laboratories. As described, the duplicate method does not permit the estimation of systematic effects from the sampling process. When the duplicate method of uncertainty estimation is utilised, the costs will increase by 10% for sampling and 30% for analysis.

Details of the procedure are given in the EURACHEM and Nordtest Guides. It is illustrated diagrammatically below for replicate design with one (left) and two (right) split levels.



Considerations when Estimating Measurement Uncertainty within the Context of Codex

When deciding on which procedure is to be used when estimating measurement uncertainty within the Codex context it is important to recognise that Codex has adopted a number of formal quality assurance measures which have to be implemented by control laboratories. In particular, such laboratories have to be:

- accredited to an Internationally recognised Standard (now with ISO/IEC 17025 Standard); such accreditation is aided by the use of internal quality control procedures,
- participate in proficiency schemes, and
- use validated methods.

It is essential that the information provided as a result of these requirements being implemented is used by laboratories when estimating their measurement uncertainties in order to avoid unnecessary work being carried out by laboratories. In Codex, where there is a high emphasis being placed on the use of "fully validated" methods of analysis, i.e. methods which have been validated through collaborative trials, information obtained from such trials can be used in many situations.

In addition information derived from internal quality control procedures may also be used to estimate uncertainties in some situations.

Values of Measurement Uncertainty Estimations

Stipulating information on the anticipated values of measurement uncertainty estimations is frequently not appreciated. However, the users of analytical data and the customers of the laboratories producing such data frequently ask for such information. They have concerns that some laboratories underestimate the size of their uncertainties and so report unrealistically small uncertainties to their customers.

For chemical analyses, using the values of S_R from collaborative trials, it would not be unreasonable to anticipate that the (expanded) analytical measurement uncertainties reported by laboratories would be of the following orders:

Concentration	Expanded Uncertainty	Range of Acceptable Concentrations*
100g/100g	4%	96 to 104g/100g
10g/100g	5%	9.5 to 10.5g/100g
1g/100g	8%	0.92 to 1.08g/100g
1g/kg	11%	0.89 to 1.11g/kg
100mg/kg	16%	84 to 116mg/kg
10mg/kg	22%	7.8 to 12.2mg/kg
1mg/kg	32%	0.68 to 1.32mg/kg
< 100µg/kg	44%	56 to 144µg/kg

However, for total measurement uncertainties it has not yet been possible to "predict" what the uncertainties are likely to be. Experimental work has suggested that for a range of systems within the food sector the sampling uncertainty is between equal to the analytical uncertainty to 4 times the analytical measurement uncertainty. Results which have been obtained are given in Table 1 below:

Table 1: Magnitude of Measurement Uncertainty including Uncertainty from Sampling

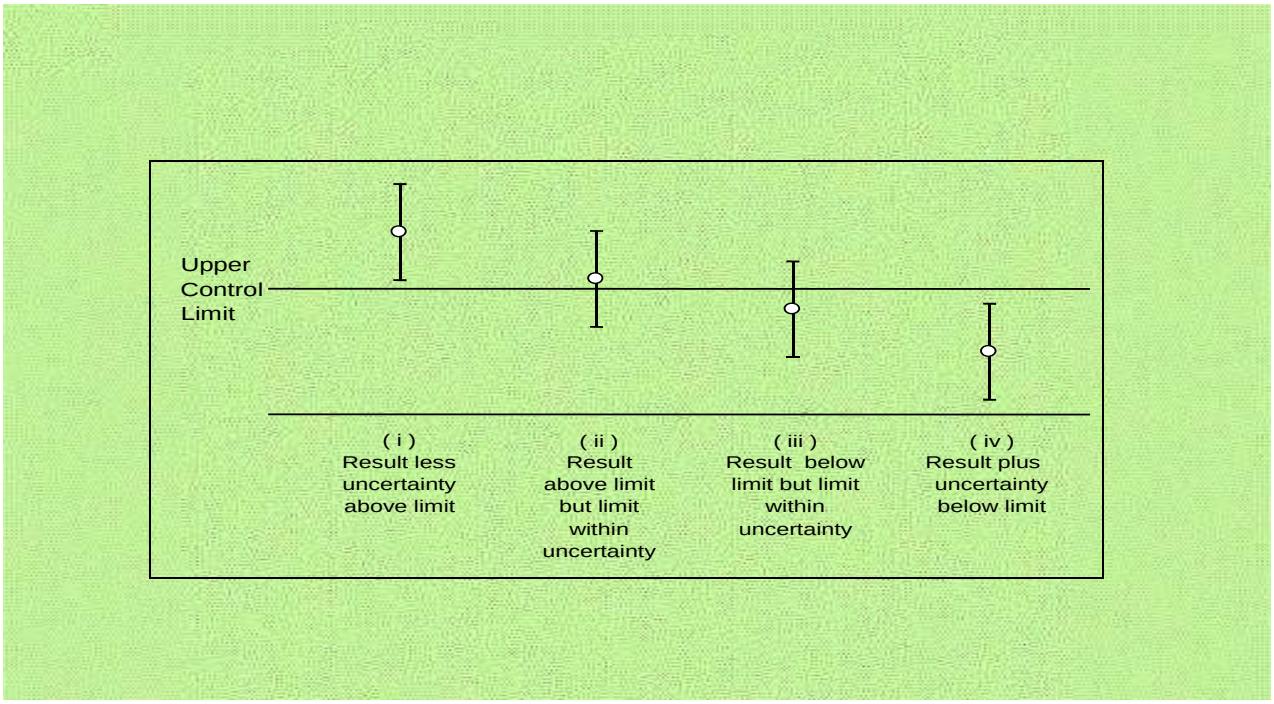
Product	Analyte	Units	mean conc	U_{meas}%	U_{samp}%	U_{anal}%
Pistachio nuts	Total aflatoxin	µg kg^{-1}	0.86	70.5	45.02	54.19
Wheat	N	% m/m	2.13	2.08	2.03	0.47
	Molybdenum (Mo)	mg kg^{-1}	0.48	13.60	12.08	6.25
	Lead (Pb)	mg kg^{-1}	0.017	93.68	76.47	54.12
Coffee(Green)	Moisture	% m/m	11.98	2.46	1.65	1.82
	Nickel (Ni)	mg kg^{-1}	4.83	31.33	22.36	21.95
Spreadable fats	Fat	% m/m	57.78	1.09	1.70	1.38
Sausages	Meat	% m/m	69.17	11.28	10.03	3.33
	Fat	% m/m	21.36	13.56	12.94	4.06

	Moisture	% m/m	55.89	5.25	5.08	1.35
Infant milk	Zinc (Zn)	µg kg^{-1}	49931	17.4	0.00	17.41
	Lead (Pb)	µg kg^{-1}	4.815	52.8	0.00	52.79
	Copper (Cu)	µg kg^{-1}	2806	13.9	4.52	13.17
	Cadmium (Cd)	µg kg^{-1}	4.654	44.5	10.49	43.23
	Arsenic(As)	µg kg^{-1}	10.29	63.51	45.50	44.31
	Tin(Sn)	µg kg^{-1}	358.8	108.23	105.47	24.29
Infant wet meals	Zinc (Zn)	µg kg^{-1}	4019.5	33.1	21.47	25.18
	Lead (Pb)	µg kg^{-1}	4.884	107.7	54.14	93.16
	Copper (Cu)	µkg^{-1}	493	33.9	31.61	12.25
	Cadmium (Cd)	µg kg^{-1}	7.575	43.7	32.61	29.04
Butter(fresh)	Moisture	% m/m	15.41	0.78	0.67	0.39
	Cadmium (Cd)	µg kg^{-1}	7.575	43.7	32.61	29.04
Butter(frozen)	Fat	% m/m	82.92	0.54	0.52	0.14
	Moisture	% m/m	15.755	2.53	2.47	0.53
	Peroxide value	meq. kg^{-1}	0.083	63.3	57.83	26.02
Lettuce	Nitrate	mg kg^{-1}	4408	16.4	14.48	7.62
(glasshouse)			3148.3	35.3	35.16	3.42
			3117.5	19.8	19.64	2.71
Tuna (fresh)	Mercury (Hg)	mg kg^{-1}	0.257	21.79	21.01	6.23
Tomatoes	Tin (Sn)	mg kg^{-1}	6.455	79.44	75.17	25.69
(tinned)	Tin (Sn)	mg kg^{-1}	74.26	20.55	19.66	6.01
			15.41	1.12	1.04	0.39
Peanut	Aflatoxin	µg kg^{-1}	20		228.00	70.80
			20			114.00 44.80
Coffee (green)	Ochratoxin A	µg kg^{-1}	5		111.60	13.28
Hazelnuts	Aflatoxin (total)	µg kg^{-1}	10		263.80	10.40

Allowance for Measurement Uncertainty

It is stated in Codex that an allowance is to be made for the measurement uncertainty when deciding whether or not an analytical result falls within the specification. This requirement may not apply in situations when a direct health hazard is concerned, such as for food pathogens. This does mean that it is important for Codex Commodity Committees, when setting specifications, to recognise that there is a difference between the numeric value in the specification and numeric value at which the specification will be enforced. Put simply this difference equates to the measurement uncertainty of the result obtained by the "enforcing laboratory". Thus, when enforcing a maximum limit, the enforcement laboratory (normally the importer) will have to deduct the value of the measurement uncertainty before deciding whether the sample meets the specification.

This is best illustrated diagrammatically in Codex Guidelines 54 (CAC/GL 54/2004.



It should be noted that the above situation will have to be interpreted with sensitivity in some instances. However, the risk of inadequate protection of the consumer may be reduced by a suitable selection of the specification – thus it is essential that the significance of measurement uncertainty deduction from the analytical result before assessing compliance is appreciated.

If the total measurement uncertainty is to be taken into account, the "error bars" become very much greater. This means that there is much more chance of situations *II and III* occurring.

Enforcement Situation

The significance of this section in the Procedural Manual is that the laboratory at importation will deduct the measurement uncertainty. If the value after deduction is still greater than the specification, then it may be stated, ***beyond reasonable doubt***, that the sample is not compliant with the specification. If sampling uncertainty is taken into account then without an alteration to a (maximum) control level, more samples will be deemed to be compliant with the control level.

It is important for the exporter to realise that in order to be sure that the exported product meets the specification the "certificated value" obtained by the producer/exported must have the uncertainty of the result added to it, and for that value to be below the specification.

By using the total uncertainty to assess compliance it means that the situation II will occur more frequently than previously.

Action to be taken by Authority Setting the Specification Level

In order to protect the consumer either:

The total measurement uncertainty when estimated must not be significantly greater that the analytical uncertainty when estimated alone, or the (maximum) specification level must be reduced to take into account the increased value of the total measurement uncertainty as compared to the analytical measurement uncertainty.

ANNEX C: AUTO-CONTROL OF THE PRODUCTION PROCESS

1. BACKGROUND

This paper explains the principles of auto-control, its advantages and disadvantages.

2. SUMMARY OF ISSUES

Auto-control is a self-monitoring system for collecting the information required to check that dairy products meet quality requirements. It makes use of the data that many manufacturers already have available as a result of their own routine in-house quality monitoring. Auto-control is not intended to replace entirely the existing system, which involves analysis of samples by an official control laboratory. It would not be introduced as mandatory procedure.

A major advantage of auto-control is that it provides a sounder basis on which to judge the quality of products seeking aid than the present system does. Control measures are needed to ensure against the risk of data manipulation by a manufacturer and these have been addressed in the draft detailed procedures. It is estimated that limited financial savings for control bodies should be gained once the system has been established with a manufacturer.

Feedback from several Member States involved in the Experts Chemists committee has indicated that introduction of auto-control would be welcomed by both manufacturers and national official control bodies.

3. INTRODUCTION

Auto-control is a system based on the official use of results of self-monitoring obtained by a factory. 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. Auto-control would not be introduced as a mandatory control procedure.

Proposals for change often give rise to concerns and questions, and in particular:

- Will the new idea work?
- Would it be worth the effort to introduce it?
- Is it necessary to change that which is currently in place?

Auto-control cannot entirely replace the existing approach based on taking samples and analysing them in an official control laboratory and is not intended to do this. However, it does offer advantages in some cases that may be worth considering and it is based on well researched and thorough scientific and statistical principles. In cases where auto-control can be applied manufacturers and control authorities should give it serious consideration.

4. WHY DO WE NEED A NEW SYSTEM?

There is currently no consistent approach to sampling applied to regulations associated with dairy products. For example, regulations pertaining to butter for manufacture give no guidance to Member States as to the number of samples that need to be taken. This has led to differing approaches in individual Member States.

Where sampling strategies have been put in place these are a compromise taking into account the costs associated with official control. Consequently decisions are taken on the basis of very few samples analysed. This means that there is very little information available to the control authority on which to base decisions regarding compliance with specification limits.

In some sectors it has been the policy to apply a tolerance to allow for analytical variability of the results obtained in official control laboratories. This carries the risk that manufacturers will seek to work up to the full limit of this tolerance particularly in cases such as moisture in butter where there are significant economic consequences for the manufacturer. The Commission has attempted to prevent manufacturers from exploiting the tolerance allowance by requiring that no more than one in five consecutive results is permitted between the specification limit and the limit plus (or minus for a lower limit) analytical tolerance. However this policy has no sound statistical basis. Experience of and in discussions with third countries has demonstrated that this rule is ambiguous and subject to dispute.

5. WHAT ARE THE ALTERNATIVES TO AUTO-CONTROL?

It is not practical on cost considerations to improve matters by significant additional effort in official control analysis. Acceptance sampling does provide an alternative. However this suffers from the same disadvantage as official control analysis in that the sampling effort per lot is too high. The basic concept involves application of a pre-determined plan to decide whether a batch of goods meets defined criteria for acceptance. It is also not necessary for every item to be in compliance with the specification limit for the product to be accepted. Acceptance sampling is not widely applied but has been adopted in EU legislation (e.g. for water content of frozen poultry) and General Principles on Sampling, based on acceptance sampling, have been adopted by the Codex Alimentarius Commission[1]. Acceptance sampling, as described by current international standards, has two further disadvantages. The statistical basis requires

discreet items, whereas butter and skimmed milk powder are continuous items. Secondly, it is assumed that measurement variability can be ignored. This may be true in cases such as measuring the length of screws but has been shown not to be the case for measuring component concentrations in products such as butter and skimmed milk powder.

6. IS AUTO-CONTROL A NEW CONCEPT?

Auto-control is soundly based on the principles of Statistical Process Control. It is a well-established technique for quality assurance widely adopted for the production of goods to defined quality specifications.

In larger factories product quality is routinely monitored, often using techniques such as infrared analysis. Manufacturers need to ensure that their product stays within specification, and to take corrective actions if product quality falls outside pre-defined limits. Therefore much of the infrastructure required to implement auto-control may (should?) already be in place at the factory. In order to make the transition to an acceptable auto-control system these available data need to be collated and recorded in an agreed way and reliable checks on product quality and data integrity need to be put into place and verified on a continuous basis.

Regulations within some sectors do already make allowance for self-checking by approved factories, e.g. within Regulation 1898/2005 provided that Member States obtain the Commissions' consent. The procedure described in Regulation (EC) No. 2535/2001 involves using the data submitted by factories in New Zealand to monitor product compliance and has been in place for several years.

7. WHAT DOES THE MANUFACTURER NEED TO DO TO SET UP AUTO-CONTROL?

Where routine monitoring of product quality is already being carried out, e.g. checking moisture content in butter, the manufacturer already has a bank of data that could be effectively used to demonstrate consistent product quality to the competent authority. Early discussions with the authority are important if the data are to be gathered in an acceptable way. It is very important that the manufacturer can demonstrate that the data presented are accurate and are not significantly different from those that would have been obtained if the official laboratory had undertaken analyses. Not only does the competent authority have to be satisfied about this, they, in turn, must demonstrate to the Commission auditors that they have made decisions based on sound data. So, ensuring that the data are "transparent", reliable and can be easily audited if necessary is very important.

Confidence in the reliability of the data will be improved by having a clear audit trail and adopting good quality assurance practices, e.g. ensuring that a named person signs off data and is responsible for both the sampling and the chemical analysis, and that if there are any changes made to records a full explanation is provided for why these were made. Laboratories working in compliance with accreditation standard ISO 17025 will be well aware of the requirements for record keeping and are likely to have all these in place.

Confidence in the accuracy of the data comes from exchange of samples with other laboratories. The competent authority can arrange for split identical samples to be analysed by the manufacturer and the control laboratory and there are well established statistical procedures for checking if there is any significant bias in the manufacturers' results. It is a good idea for the manufacturer to participate in a regular proficiency testing scheme if one is available. Such schemes involve analysis of samples by a number of laboratories and comparison of the manufacturers' results with consensus values. It is also worthwhile encouraging exchange visits between the control laboratory and the manufacturers' laboratory to see each other's procedures and discuss any differences in analytical methodology.

Experience has frequently shown that even what may seem to be insignificant differences in analytical methods can have a significant impact on the results.

The introduction of an acceptable auto-control system cannot happen very quickly. It is also essential to keep in mind what the data will have to show once they are assembled. The principle behind auto-control is that at least 95% of all data must be within specification limits. Conversely, no more than 5% of the values are allowed to exceed the limit. This requires that the mean value of the data lies somewhere below the actual specification limit (for a maximum specification). Just how far below depends on how tight the spread of data (standard deviation) is. Manufacturers working with good quality control and small standard deviation values will be able to adopt a long term process mean that is close to the specification limit. Before embarking on collecting data for submission there should be sufficient confidence that satisfactory values for long term mean and standard deviation are likely to be found.

As a guideline at least 200 control results should be collected on at least 20 different production days. It is recommended that a constant sample size is used (e.g. 10) as this simplifies the statistics which may be used. These data are used to calculate the two most important statistical parameters used in auto-control; the long-term process standard deviation and the long term process mean. The control data are plotted graphically with the results on the "y-axis" against time on the "x-axis"; this is a Shewhart chart. Examples are shown in Figures 1 and 2 (see below). Provided that the data are not distributed in an unusual manner statistical theory predicts that if the process mean is set at "Specification limit – 1.645 x process standard deviation" then no more than 5% of results should exceed the limit.

For example, in the case of moisture in butter the process mean would be set at 16% - 1.645s (where s = long term process standard deviation).

8. HOW DOES THE MANUFACTURER DEMONSTRATE SATISFACTORY CONTROL AFTER THE SYSTEM HAS BEEN PROVISIONALLY ACCEPTED?

Ideally once the process mean and standard deviation have been fixed and provisionally accepted by the control authority the system runs without further intervention. But this will never happen. There are bound to be variations in the mean and standard deviation, and it is essential that the competent authority can ensure that the data continue to be a true reflection of the manufacturing process. Figures 1 & 2 illustrate what would happen in the case of moisture in butter if the process average increases from 15.8 (Figure 1) to 15.9 (Figure 2) but with no change in the standard deviation. The control limit is 16.0% moisture.

It will be necessary to continue to check the results against those of the control laboratory. The control authority can judge just what level of checking takes place bearing in mind factors such as the experience of the manufacturer; whether there appear to be problems either with the data or suspected problems with data reliability. However, it is to be expected that as more data are collected, and all parties gain in experience, a robust system will develop that maximises the benefits to all concerned with real gains in efficiency and effectiveness.

9. 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.

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

- The status of being officially authorised to proceed with auto-control gives a potential marketing benefit, and potentially higher credibility rating, having official approval behind the system.

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

- 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.

11. 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.

12. WOULD AUTO-CONTROL BE COMPULSORY?

No. The system would be applied on a voluntary basis with manufacturers submitting data and working in co-cooperation with the control authority to gain acceptance.

13. 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 Lab. 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.
- 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.

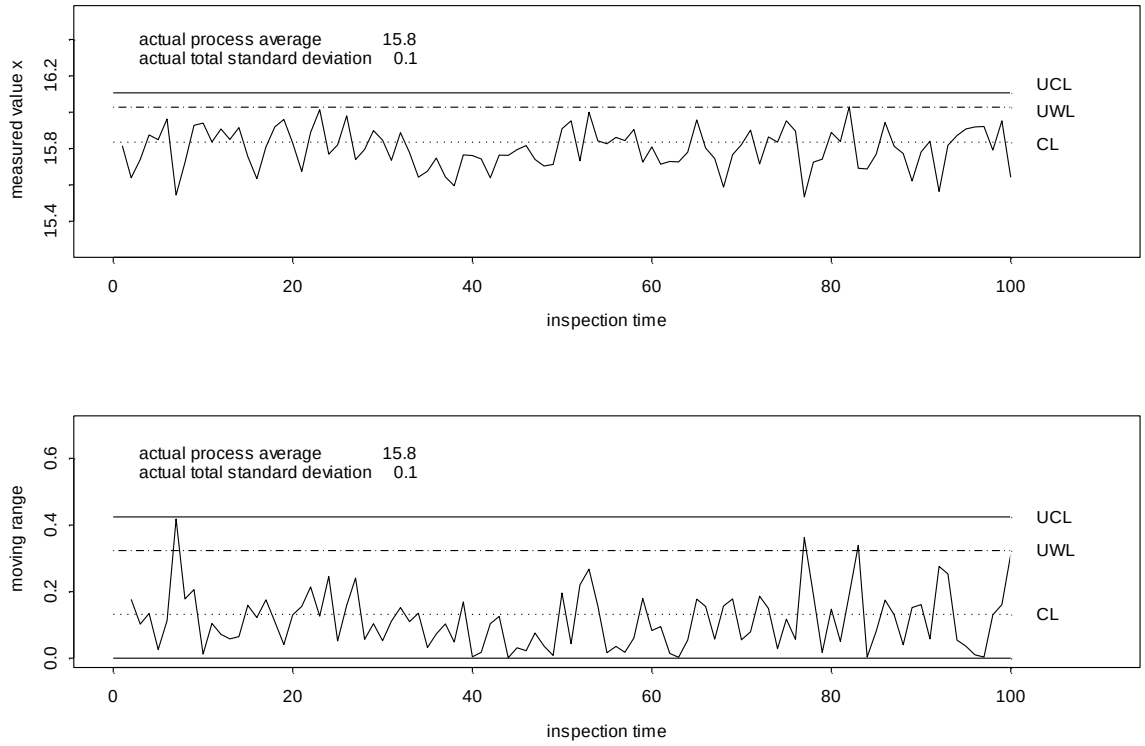
14. WHAT IF THERE ARE DISPUTES BETWEEN THE MANUFACTURER AND CONTROL AUTHORITY?

There are no set prescriptive procedures for dealing with disputes, but guidelines are being developed particularly in the field of international trade and these would be useful for auto-control. In the event of a dispute the Codex guidelines for settling deputes over analytical test results could be consulted.

15. WHAT HAPPENS IF THE SYSTEM IS NOT WORKING SATISFACTORILY FOR EITHER THE MANUFACTURER OR THE CONTROL AUTHORITY?

Both parties need to work together to ensure the data are demonstrably reliable. As long as the control authority is satisfied that data accurately reflect the product composition routine checking may proceed at a fairly low level. If there appear to be inconsistencies in the data the control authority is likely to increase the frequency and rigour of checks. Ultimately the control authority would have the option of suspending licence to use Auto-control with an option to re-instate only if the manufacturer can demonstrate that all shortcomings have been addressed.

Figure 1 : moisture control (target process average 15.80%, target total standard deviation 0.1166%)



ANNEX D: INSTRUCTIONS ON CODEX SAMPLING PROCEDURES BASED ON ACCEPTANCE SAMPLING PROCEDURES

These draft Instructions on Codex Sampling Procedures are intended for use by Codex Committees in their review of Codex Standards regarding sampling or in the selection of appropriate sampling plans in the development of standards. They are acceptance sampling based and give simple information on what is involved in such procedures.

CONTENTS

Section

APPENDICES

1. INTRODUCTION AND GENERAL BACKGROUND

See introductory text to this discussion paper.

2. ASPECTS OF SAMPLING AND ACCEPTANCE PROCEDURES

The different aspects of sampling and lot acceptance procedures should be clearly separated in any Codex sampling procedure. These aspects are:

(a) The procedure for physically obtaining items from a lot to form a sample;

(b) The number of items to be taken for analysis from a lot;

(c) Interpretation and consideration of the analytical results obtained; and

(d) Decision on acceptability of lot from which the sample was taken.

These Instructions concentrate on aspects (b), (c) and (d).

3. TYPES OF SAMPLING PLANS

The General Principles for the Establishment or Selection of Codex Sampling Procedures (see Appendix I) state or imply that the following combinations of types of characteristics in the Codex Standards and types of sampling plans should be considered:

Type of Characteristic	Type of Sampling Plan
3.1 Commodity defects (e.g. as applied to visual defects such as loss of colour, mis-grading extraneous matter etc.)	"Attribute" (e.g. as in Codex Sampling Plans for Pre-packaged Foods, CAC/RM 42-1969)
3.2 Compositional characteristics: these may be normally distributed (e.g. most analytically determined compositional characteristics such as loss on drying in white sugar) or they may be non-normally distributed (e.g. analytically determined compositional characteristics in some commodities).	"Variables with unknown standard deviation" for normally distributed characteristics and "attribute" for characteristics whose distributions deviate significantly from normal.
3.3 Net contents (as applied to pre-packaged foods)	Sampling plan to be in agreement with the recommendations included in Section 7.
3.4 Health-related properties (e.g. in the assessment of microbiological spoilage, microbial hazards, sporadically occurring chemical contaminants etc.)	Specified sampling plans to be proposed appropriate to each individual situation (e.g. the microbiological spoilage, IDR 113 and the ICMSF Standards). Plans to detect incidence rates in a population may be used.

4. PROCEDURE TO BE FOLLOWED BY CODEX COMMODITY COMMITTEES WHEN DEVELOPING A SAMPLING PLAN

The procedure to be used by Codex Commodity Committees when developing a sampling plan is given in detail in flow-chart form in Appendix II.

It should be noted that users and Codex Commodity Committees are required to consider, for any particular Standard, the following:

4.1 Types of characteristics

The various characteristics should be classified into the types previously outlined in these Instructions (see Section 3).

4.2 Choice of one or more Sampling Plans

It is to be expected that different sampling plans may have to be included in the Standard in the same way as there are different methods of analysis already given in each Standard.

4.3 Choice of Type of Sampling Plan

It is necessary to decide, in principle, the type of sampling plan which will be attracted to each characteristic. In particular, it is necessary to indicate whether the acceptance sampling plans referred to in the General Principles for the Establishment or Selection of Sampling Procedures are to apply. If they are not to apply, the reason why not should be positively stated when the sampling plan is proposed.

4.4 Divergence between Codex and National Standards

It is necessary to recognise that different sampling and enforcement regimes exist in the various countries which are members of the Codex Alimentarius Commission. It should, therefore, be appreciated that Codex Standards cannot be designed to accord with all such enforcement systems. It is possible, although not desirable, for Member Countries to accept a provision in a Codex Standard without also accepting the methods of sampling and analysis which the Codex Commission has recommended for use in determining the value of the provision.

4.5 Standard Sampling Plans

Sampling plans which have been developed and published by International (or National if appropriate) Organisations and which have a direct bearing on the commodity or Standard under consideration should be considered. For example, some of the plans in Appendix 1 are based on ISO 2859 and ISO 3951.

Such Organisations tend to publish sampling plans or instructions on the procedures to be employed to physically obtain samples: they should be selected unless there are positive reasons for not doing so.

4.6 Sampling vocabulary

The sampling vocabulary, given in Appendix III to these Instructions should be used. The vocabulary includes all the terms which are likely to be required by Codex Commodity when sampling plans are developed. Sampling plans developed by non-Codex Organisations, and included in the Codex Alimentarius should be re-drafted to conform to the Codex vocabulary.

4.7 Mathematical Implications of the Sampling Plans Selected

In selecting a variables or attribute plan, as appropriate, the mathematical probabilities associated with the selection should be borne in mind. These are described in Section 8 of these Instructions.

The mathematical values given in these Instructions have been taken from tables published by the International Organisation for Standardisation (2) and (3).

5. DIAGRAMMATIC REPRESENTATION OF POSSIBLE CODEX SAMPLING PLANS

Possible types of sampling plans which might be selected by Codex Commodity Committees are shown diagrammatically in Appendix IV. It should be noted that plans (1) and (2) are the recommended procedures but other options are described. If Commodity Committees select other options, the rationale for doing so must be stated when the plan is sent for endorsement (see Section 4.3).

6. DESCRIPTION OF AND FORMULAE TO BE USED IN ACCEPTANCE SAMPLING PLANS ADOPTED BY CODEX

Attribute or variables plans with unknown standard deviation are recommended to be used by Codex Commodity Committees by the General Principles for the Establishment or Selection of Codex Sampling Procedures. A description of the mode of use of these two types of plans, together with relevant formulae associated with their use, is given diagrammatically in Appendix IV and in detail in Appendix V of these Instructions.

7. NET CONTENTS

The plans suggested in these Instructions do not apply to sampling for net contents.

8. SELECTION OF VALUES OF MATHEMATICAL PARAMETERS FOR THE OPERATION OF CODEX SAMPLING PLANS

8.1 Choice between variables and attribute plans

Where inspection of an item in a lot is made by recording whether it is defective or non-defective (or by counting the number of defects in the sample) it is necessary to use an attributes plan. Where inspection involves making a measurement of some kind on each item, on a continuous scale, and the distribution of these measurements can be verified to be at least approximately normal form, it is appropriate to use a variables plan, although an attributes plan may be used if desired. In the latter case the item is deemed to be defective or non-defective according to whether or not the numerical measurement lies beyond the specification for the product.

A variables plan is more economic than an attributes plan to operate as it requires a smaller size of sample for the same acceptable quality level (AQL) and consumer risks of accepting poor quality.

8.2 Acceptable Quality Level

The initial parameter to be considered is the acceptable quality level (AQL). The AQL may be considered as the maximum percentage of defective items (or the maximum number of defects per hundred units) in the lot which is satisfactory as a process average in continuous production. Lots of AQL quality will be accepted most of the time (ie more than 90%) that they are submitted for sampling. For a given sample size the lower the AQL of the plan the greater is the protection given to the consumer and buyer against accepting lots with defective items. Equally, the greater is the onus on the producer to manufacture to a sufficiently high standard of quality. Any value of AQL which is selected must be one which is practically realisable and economically viable.

The sampling plan for defective units in prepackaged foods uses an AQL in the region of 6.5% with an associated lot acceptance of 95% or more. There is a tendency for this plan to be misapplied to compositional characteristics, and for the specified AQL to be taken as the ‘norm’ whenever Codex sampling plans are discussed. However, it should be recognized that the selection of the value of the AQL to be used is dependent on the specific characteristic under consideration and its relevance (economic or otherwise) to the standard as a whole. In other words some weighting should be given to certain characteristics (e.g. in critical, major or minor defects).

It is suggested that Codex Commodity Committees consider one of eight values of AQL, namely in the region of 0.1, 0.25, 0.65, 1.0, 2.5, 4.0, 6.5 or 10.0% as appropriate to the characteristic in question. Characteristics which may be "health-risk" associated should attract a low value AQL (i.e. 0.1 to 1.0%) whereas those for compositional characteristics such as fat, moisture etc, could attract a higher value AQL (e.g. 6.5% and 10% is often used for milk products.

The sampling plans and associated quality levels, as given in Appendix V, are referenced, as far as is possible to the right AQL values indicated above. It should be appreciated that, due to derivational limitations, not all of the above suggested AQLs are possible for each referenced sampling plan.

8.3 Size of sample to be taken

The effect of the numbers of items taken on the chance of accepting a lot is given in Appendix V. Particular attention should be paid to the quality of a lot which has a 10% chance of acceptance as this is indicative of the risk of reducing the sample size for analysis.

Consideration must be given to the nature of the items forming the sample. Where the produce is pre-packed this does not normally present a problem since each package will constitute an item for the purpose of sampling. If the product is supplied in bulk it will be necessary to take an increment and each increment will constitute a sample item (unless two or more increments are blended together).

For this reason, in order to reduce the risk of accepting large numbers of defective items, it is usual to increase the sample size as the lot size increases.

Note that it is not necessary to continue to inspect the units in a sample after a decision is certain from the items already inspected. Thus, in inspecting to the plan n=13, c=2, if the first three items are found to be non-conforming, the lot may be rejected without necessarily inspecting the remaining 10 units. Similarly, inspection could cease after 11 conforming units are found.

8.4 Inspection Level

The risk of accepting examined lots with a given percentage of defective items is determined by the sampling plan chosen. Clearly, however, the actual number of defective items in the lot will depend on the size of the lot.

Tables (1, 3) showing recommended sample sizes to be taken for different lot sizes, corresponding to different levels of inspection, are shown in Appendix V. These are intended as a guide and it is not mandatory to use either the precise values quoted for lot sizes or as many range sub-divisions. Two opposing factors need to be considered in deciding on the inspection level to use. These are the consequences of passing lots with a higher number of defective items and the overall cost of the total sampling operation, including analysis.

The inspection level numbers (1 to 5) correspond to similar risks in the operation of attribute and variable plans. For a given AQL the lower the inspection level number the greater is the risk of passing poor quality lots. It is suggested that, depending on the implication, levels 2 to 4 be regarded as the normal levels for sampling lots. If health risks are not involved and sampling costs are a major consideration, a lower level may be used. Where health risks are of major concern inspection level 5 may be adopted.

Whatever plan is selected, the actual quality of lots (in percent defective items) which, if submitted, would be passed 95%, 50% and 10% of the time, is given in Appendix V.

8.5 Operating the Sampling Plan

When the AQL, level of sampling and type of plan have been fixed, the characteristic for a decision on whether to accept or reject a lot is indicated in the Tables of Appendix V. In the case of an attributes plan the decision rests on the number of defective items or defects observed in the sample.

In the case of a variables plan the mean values of the measurement made on each of the items in the sample and the standard deviation are computed and form the basis of the decision. Provided that the difference between (taken in the appropriate direction) the sample's mean value and the specification limit for the product equals or exceeds the standard deviation multiplied by a certain constant, the lot is accepted. Values of the acceptability constant are given in Table 4 of the Appendix V.

Note: one consequence of using a variable sampling plan is that circumstances may arise where a lot is rejected even though the sample itself does not contain any individual defective items. The reasons for these circumstances are sometimes difficult to explain to those not familiar with the detailed operation of sampling plans. If and when this circumstance does arise, it is liable to cause resentment towards, and disbelief in, sampling procedures. Such resentment should therefore be anticipated.

9. CONCLUSIONS

These Instructions serve as a guide to Codex Committees on the approach that should be taken in the selection of sampling plans, and in particular the need to select the plans concurrently with the characteristics under consideration. They also give numerical values which can be included in such sampling plans.

10. REFERENCES

(1) International Organisation for Standardisation 'Agricultural Food Products - Layout for a Standard Method of Sampling from a Lot', ISO/DIS 7002: 1984.

(2) International Organisation for Standardisation 'Sampling Procedures and Tables for Inspection by Attributes', ISO 2859: 1974.

(3) International Organisation for Standardisation. 'Sampling Procedures and Charts for Inspection by Variables for Percent Defective', ISO 3951: 1981.

(4) Codex Alimentarius Commission 'FAO/WHO Codex Alimentarius Sampling Plans for Pre-packaged Foods (1969) (AQL 6.5)', CAC/RM 42-1969.

APPENDIX I: GENERAL PRINCIPLES FOR THE ESTABLISHMENT OR SELECTION OF CODEX SAMPLING PROCEDURES

1. Purpose of Codex Methods of Sampling

Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard. The sampling methods are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.

2. Methods of Sampling

(A) Types of Sampling Plans and Procedures

(a) Sampling Plans for Commodity Defects:

These are normally applied to visual defects (e.g. loss of colour, mis-graded for size, etc.) and extraneous matter. They will normally be attribute plans, and plans such as those included in CAC/RM 42-1969 may be applied.

(b) Sampling Plans for Net Contents:

These are sampling plans which apply to pre-packaged foods generally and are intended to serve to check compliance of lots or consignments with provisions for net contents.

(c) Sampling Plans for Compositional Criteria:

Such plans are normally applied to analytically determined compositional criteria (e.g., loss on drying in white sugar, etc.). They are predominantly based on variable procedures with unknown standard deviation.

(d) Specific Sampling Plans for Health-related Properties

Such plans are generally applied to heterogeneous conditions, e.g., in the assessment of microbiological spoilage, microbial by-products or sporadically occurring chemical contaminants. Attribute plans to detect incidence rates in a population may be appropriate.

(B) General Instructions for the Selection of Methods of Sampling

(a) Official methods of sampling as elaborated by international organisations occupying themselves with a food or a group of foods are preferred. Such methods, when attracted to Codex standards, may be revised using Codex recommended sampling terms (to be elaborated)[9].

(b) The appropriate Codex Commodity Committee should indicate, before it elaborates any sampling plan, or before any plan is endorsed by the Codex Committee on Methods of Analysis and Sampling, the following:

(i) the basis on which the criteria in the Codex Commodity standards have been drawn up (e.g. whether on the basis that every item in a lot, or a specified high proportion, shall comply with the provision in the standard or whether the average of a set of samples extracted from a lot must comply and, if so, whether a minimum or maximum tolerance, as appropriate, is to be given);

(ii) whether there is to be any differentiation in the relative importance of the criteria in the standards and, if so, what is the appropriate statistical parameter each criterion should attract, and hence, the basis for judgement when a lot is in conformity with a standard.

(c) Instructions on the procedure for the taking of samples should indicate the following:

(i) the measures necessary in order to ensure that the sample taken is representative of the consignment or of the lot;

(ii) the size and the number of individual items forming the sample taken from the lot or consignment;

(iii) the administrative measures for taking and handling the sample.

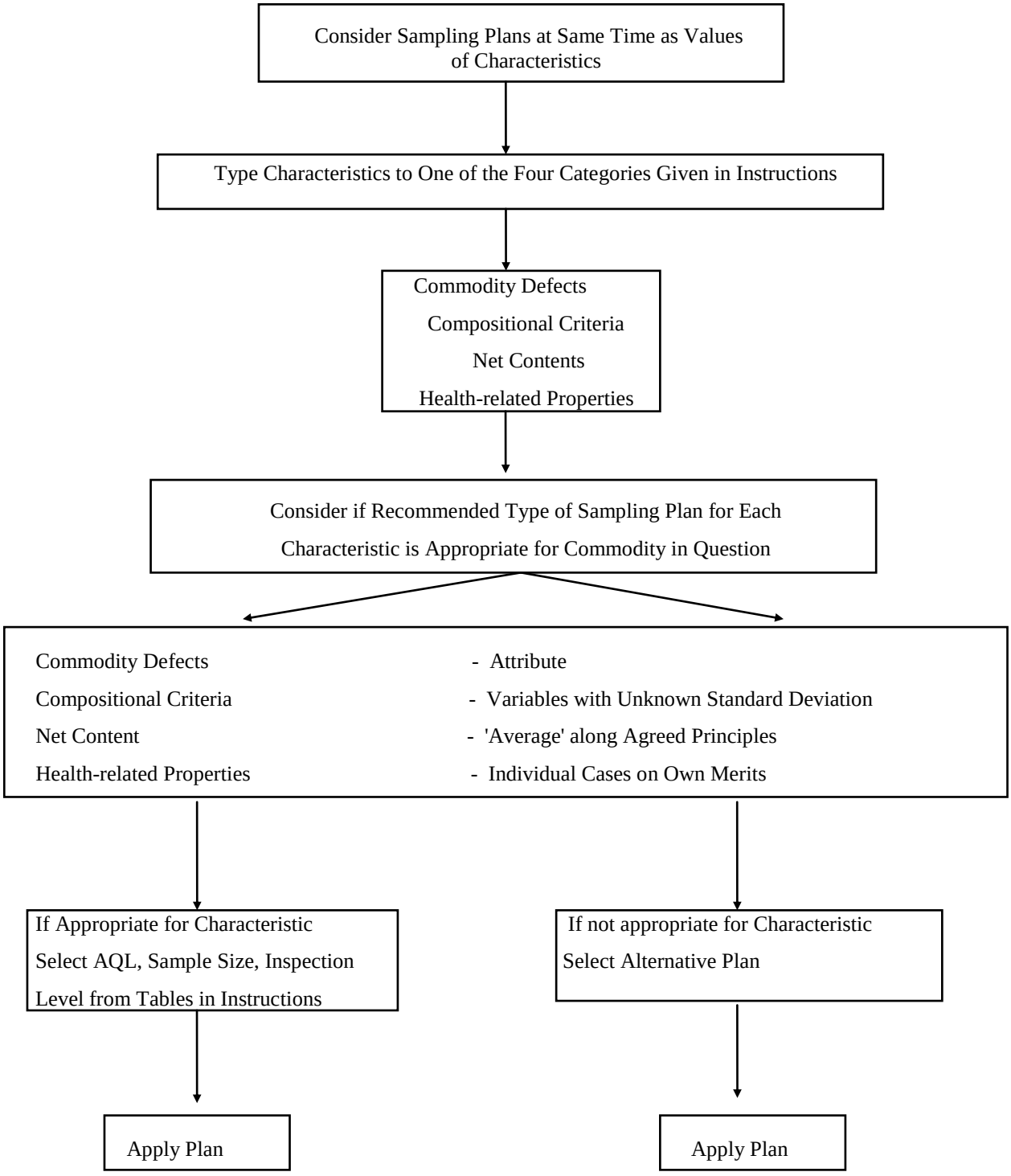
(d) The sampling protocol may include the following information:

(i) the statistical criteria to be used for acceptance or rejection of the lot on the basis of the sample;

(ii) the procedures to be adopted in cases of dispute.

[9] See Appendix III

APPENDIX II: FLOW-CHART OF PROCEDURE FOR DEVELOPMENT OF CODEX SAMPLING PLANS



APPENDIX III: SAMPLING VOCABULARY AND DEFINITIONS OF TERMS TO BE USED IN CODEX SAMPLING PROCEDURES

The following terms should be used in Codex documents whenever sampling and acceptance procedures are included or referred to in such documents.

1. Acceptability Constant (k)

The constant multiplier associated with a variable sampling plan for percentage of defective units and is dependent on sample size and acceptable quality level.

2. Acceptable Quality Level (AQL)

For a given sampling plan the quality of a lot expressed as the percentage of defective items (or defects per 100 units) in the lot that is considered satisfactory as a process average and is associated with a high probability of acceptance (usually in the region of 95%).

NOTE - In sampling by variables other acceptance criteria may be defined. For example, acceptable quality also may be endorsed as the quality of a lot expressed as the true mean of the inspected variable often associated with its standard deviation or range that, for purposes of sampling inspection, can be considered satisfactory as a process average.

Sampling plans indexed by AQL are intended primarily to be used for a continuing series of lots. These plans may also be used for the inspection of lots in isolation but, in this case, the user is strongly advised to consult the operating characteristic curves to consult the desired protection.

3. Acceptance Number (c)

For a given attribute sampling plan, the maximum number of defective items (or of defects) allowed in the sample that permits acceptance of the lot.

4. Attribute

See characteristic (No. 7).

5. Batch

See Lot. Lot is the preferred term to be used in Codex documents.

6. Bulk Sample/Blended Bulk Sample

A combined aggregation of the increments.

7. Characteristic

A property which differentiates between the items of a given lot into acceptable and unacceptable items. The differentiation may be either quantitative (by variables) or qualitative (by attributes).

NOTE - Measurable characteristics (variables) may also be converted to an attribute by determining whether the measurement is in a certain range of values.

8. Consignment

A quantity of some commodity delivered at one time and covered by one set of documents. The consignment may consist of one or more lots or parts of lots.

9. Consumer Risk (CR)

For a given sampling plan, the probability of acceptance (usually in the region of 10%) of a lot having the rejectable quality level (see 22).

NOTES

(a) The probability region of acceptance will generally be chosen dependent on the severity of defects (see 10); i.e. as the defect becomes a greater hazard to health, the probability of acceptance is decreased.

(b) Consumer may also be taken to mean buyer or purchaser.

10. Defective Item

An item which does not meet the specification limit. In the case of variables, the measurement lies beyond the specification limit; in the case of attributes, the item does not meet the requirements (i.e. has one or more defects).

NOTE - In the order of significance of the specifications, defects can often be classified as follows:

(a) Critical defect: A defect that, according to judgement and experience, is likely to result in hazardous or unsafe conditions for individuals using, maintaining or depending upon the products, or that is likely to prevent performance of the function of a major product;

(b) Major defect: A defect other than critical, that is likely to result in a failure or to reduce materially the usability of the product for its intended purpose.

(c) Minor defect: A defect that is not likely to reduce materially the usability of the product for its intended purpose or that is a departure from established specifications having little bearing on the effective use or operation of this product.

11. Increment

A quantity of material taken at one time from a larger body of material using a sampling device.

NOTE - Increments may be tested individually aiming at estimation of the variation of any characteristics throughout a lot (or between lots).

12. Inspection

The process of examining, measuring, testing, gauging or otherwise comparing the unit with applicable requirements.

NOTES

(a) Inspection may often mean the looking over of the lot.

(b) A suitable level of inspection, expressed in statistical or other terms, should be chosen of which the rate is inversely proportional to the stability of the process average.

13. Inspection level

The term used to indicate the relative amount of sampling performed on lots of a product or class of products

14. Item

(a) An actual or conventional object on which a set of observations may be made.

(b) A defined quantity of material on which a set of observations may be made.

NOTE - The English terms "individual" and "unit" are sometimes used as synonyms of "items".

15. Laboratory Sample

A sample prepared and sent to a laboratory for inspection or testing.

16. Lot

An identified quantity of some commodity, manufactured under conditions that are presumed uniform.

NOTES

(a) Uniformity conditions consist of several features, for example products supplied by one producer always using the same production process, where production is stable and the quality characteristic is distributed according to the normal distribution or a close approximation to the normal distribution. Note that specialist subdivisions may be made.

(b) Consequently the term lot (or batch) shall mean inspection lot (batch) in sampling i.e. a quantity of material or a collection of items (a population) from which a sample is to be drawn and inspected. It may differ from a collection of units designated as a lot, for example for production shipment.

17. Lot size

The number of items or quantity of material constituting the lot.

18. Operating Characteristic Curve (OC curve)

A curve showing, for a given sampling plan, the probability of acceptance of a lot as a function of its actual quality.

19. Probability of Acceptance

The probability that a lot of a given quality will be accepted by a given sampling plan.

NOTE - Although the term acceptance implies that the lot conforms to specifications, it does not necessarily permit sale of the lot which may be rejected by criteria not covered by the sampling plan.

20. Probability of Rejection

The probability that a lot of a given quality will be rejected by a given sampling plan.

NOTE - Although the term rejection implies that the lot does not conform to specifications, it does not necessarily prevent sale of the lot.

21. Producer's Risk (PR)

For a given sampling plan, the probability of rejection (usually in the region of 5%) of a lot having a quality level equal to the AQL.

22. Rejectable Quality Level (RQL): (Limiting Quality Level)

Quality of a lot expressed as the percentage of defective items (or defects per hundred units) in the lot which is considered to be unacceptable as a process average in continuous production and is associated with a low probability of acceptance (usually in the region of 10%).

NOTE - This quality level may correspond to the critical number of defectives observed in sampling inspection (ie lot tolerance percent defectives) or to a mean of a variable to which the actual mean is compared.

23. Sample (general term)

One or more items or increments taken at random from a population (lot or consignment) intended to provide information representative of the population (lot or consignment).

24. Sample Size (n)

The number of items or quantity of material constituting the sample.

25. Sampling

The procedure used to draw and constitute a sample.

26. Sampling Plan

The rules stating the sample size to be taken from a lot and the acceptance/rejection criteria to serve as the basis for a decision as to the acceptance or rejection of the lot.

27. Standard Deviation (s)

The positive square root of the variance. The variance is a measure of dispersion based on the mean squared deviation from the arithmetic mean.

Thus for a series of n observations $x_1, x_2, \ldots\ldots x_n$, with mean

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

the expression

$$s = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(x_i - \bar{x})^2}$$

would be used. Other forms of this expression may be used for computational convenience.

28. Variable

See characteristic (no 7).

29. Variance

The variance is a measure of dispersion based on the mean squared deviation from the sample mean.

$$\sigma^2 = \frac{1}{n-1}\sum_{i=1}^{n}(x_i - \bar{x})^2$$

NOTE:

Depending on the cases considered. It may be advantageous to divide the sum of the squared deviations from the arithmetic mean by the number of deviations, or by that number minus 1 to achieve an unbiased estimate of the variance of the population from which the observations came.

APPENDIX IV: DIAGRAMMATIC REPRESENTATION OF POSSIBLE CODEX SAMPLING PLANS

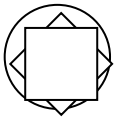
The various possible types of Codex sampling plans are explained diagrammatically below.

Symbols

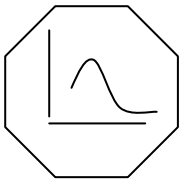
Individual items within a lot

Analysis of item or blended bulk sample

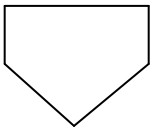
Decision on whether concentration of item meets specification



Mix samples into a homogeneous blended bulk sample



Prepare estimate of distribution curve of concentration within units from analytical measurements.

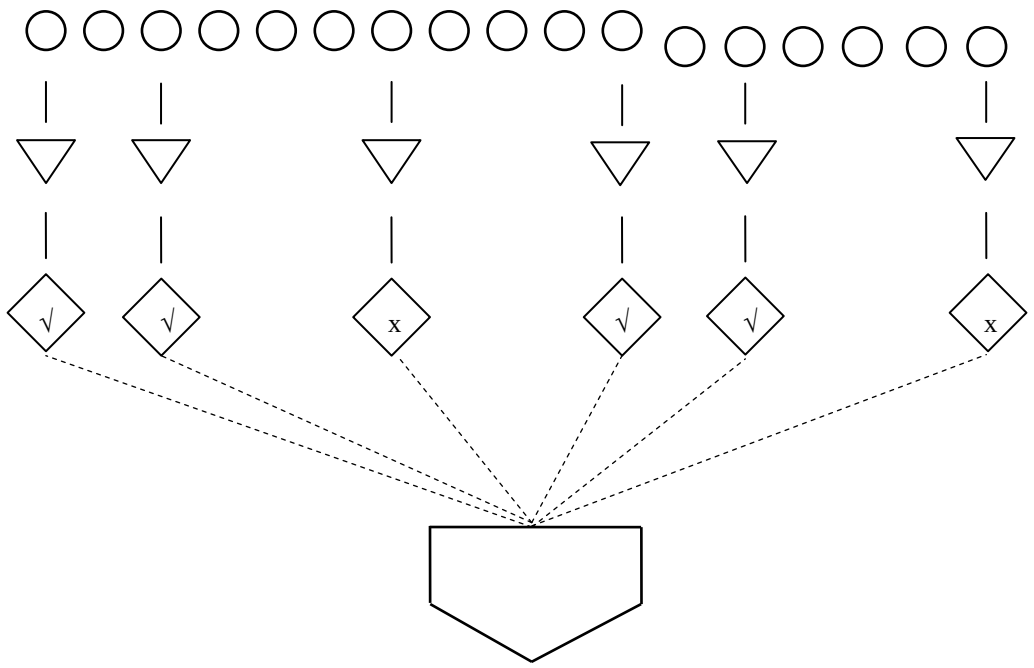


Decision on whether analysis of sample indicates lot meet specifications for characteristic in Codex Standard

.

APPENDIX V: DESCRIPTION FORMULAE AND NUMERICAL VALUES TO BE USED IN CODEX SAMPLING PLANS

1. Attribute Plans for Proportion Defective



Procedure

1. Set AQL.
2. Sample prescribed number of discrete items ▽ from lot ○
3. Analyse each item individually √ satisfactory

   x unsatisfactory
4. Let x = number of defective items in the sample; then if x < c, accept the lot: if x > c, reject the lot.
5. If c = 0, then akin to an each-and-every-item-must-comply system.

Sampling by attributes is sampling whereby either the item or the product is classified as defective or non-defective with respect to a given requirement or set of requirements.

"Item" and "defective" are defined in Appendix III.

The number of defective items, c, permitted in the samples. For different AQL levels, and probabilities, is given in Table 2. The lot is accepted when the number of defective items equals or is less than c.

1. Sample Size

The number of items to be inspected from lots of different sizes as five different levels of inspection is given in Table 1.

2. Operating Characteristics

The percentage of defective quality items in submitted lots having 95%, 50% and 10% chance of being accepted by the Sampling Plan are given in Table 2.

NOTES

a. Sample size represents the number of items randomly selected from the lot.

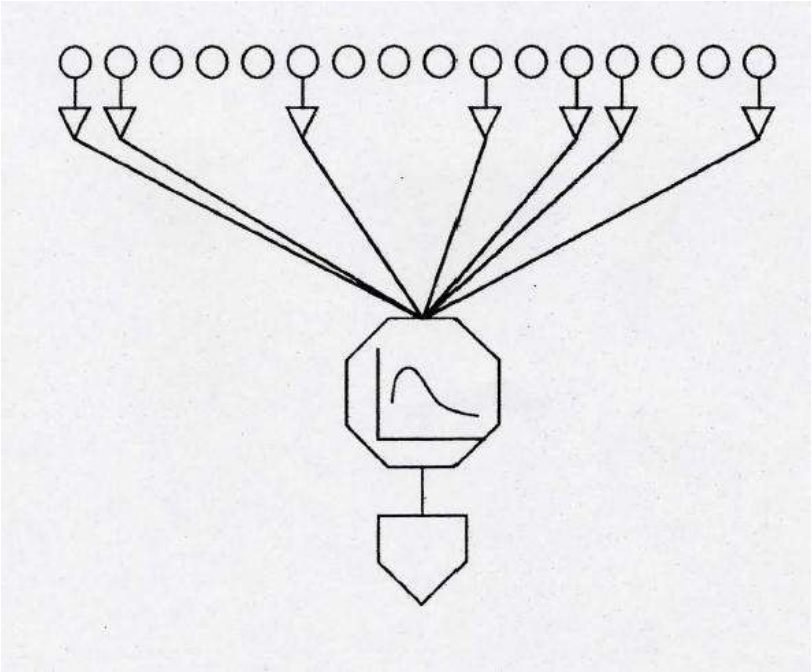
b. Chance of acceptance corresponds to the percentage of occasions on which submitted lots of the quality indicated are likely to be accepted by the Sampling Plan.

c. Accept the lot if the number of units of rejectable quality in the sample of size n is equal to or less than c.

d. Type of plan recommended for commodity defects. Statistical probabilities associated with plan given in Instructions. Best suited for simple yes/no situations where analysis is not expensive, though can be applied to

compositional characteristics where defect is defined or when concentration is greater than a maximum specification (or less than a minimum specification).

2. Variables Plan for Proportion Defective: Unknown Standard Deviation



Procedure

1. Set AQL
2. Sample prescribed number of discrete items ▽ from lot ◯
3. Analyse each item individually.
4. Calculate mean $\bar{x}$ and standard deviation (s). Whether that standard deviation includes the sampling as well as analysis component should be clearly defined.
5. Calculate to see if proportion defective is exceeded from given formula ($\bar{x} \leq$ U - ks or $\bar{x} \geq$ L + ks) where U is the upper specification limited and L is the lower specification limit.
6. Accept/reject lot if proportion defective criterion is satisfied/exceeded.

Sampling by variables is sampling whereby the values of a specified criterion for a set of items forming the sample are measured on a continuous scale and the values used to determine the acceptability or otherwise of the lot from which the items are taken.

The lot is accepted when:

$$\bar{x} \leq U - ks$$

or

$$\bar{x} \geq L + ks$$

Where

$\bar{x}$ is the mean value of the characteristic under consideration in the sample as is

$$\bar{x} = \frac{1}{n}\sum_{1}^{n} x$$

U is the upper specification limit

L is the lower specifications limit

k is the constant multiplier associated with the scheme

s is the sample estimate of the criterion standard deviation and is given by:

$$s = \sqrt{\frac{\Sigma(x-\bar{x})^2}{n-1}} = \sqrt{\frac{\Sigma x^2 - (\Sigma x)^2 / n}{n-1}}$$

Where

x is an individual result on each item in the sample

n is the number of items in the sample

Numerical values for k are given in Table 4.

1. Sample Size

The number of items to be inspected from lots of different sizes at five different levels of inspection are given in Table 3.

2. Operating Characteristics

The percentage of defective quality items in submitted lots having 95%, 50% and 10% chance of being accepted by the Sampling Plan is given in Table 4.

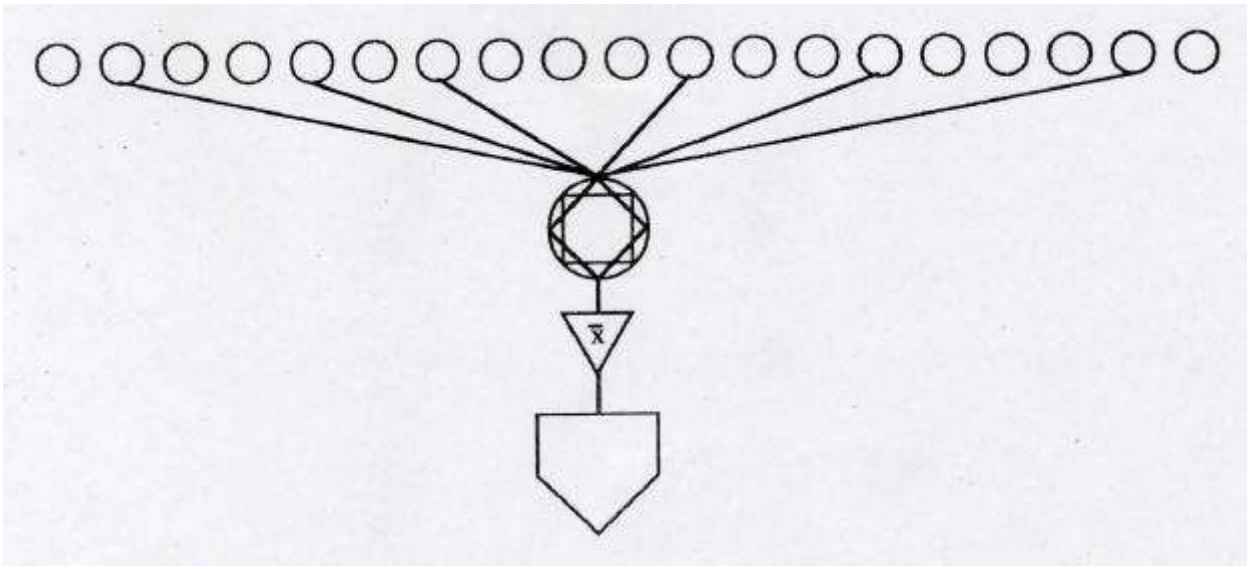
NOTES

a. Sample size represents the number of items randomly selected from the lot.

b. Probability of acceptance corresponds to the percentage of occasions on which submitted lots of the quality indicated are likely to be accepted by the Sampling Plan.

c. Type of plan recommended for compositional criteria. Statistical probabilities associated with plan given in Instructions. Need to carry out separate analyses of a characteristic with a continuous scale of measurement. Could be expensive to carry out if number of items and cost of analysis is high. X is less than specification limit U in a satisfactory lot if considering a maximum value characteristic. Results of analysis can be used to plot distribution of value of characteristic in an item analyzed. Can set a maximum or minimum tolerance ("cut-off") point for any one item.

3. Variables Plan for Proportion Defective: Known Standard Deviation



Procedure

1 Set AQL.

2. Establish σ, standard deviation of lot, before analysis.

3. Sample prescribed number of discrete items from lot.

4. Combine items to form one blended bulk sample 

5. Analyse blended bulk sample 

6. Calculate to see if lot satisfactory using formula and known standard direction of lot ($\bar{X} \leq U - k\sigma$ or $\bar{X} \geq L + k\sigma$ to accept).

Because of the necessity for knowledge of the standard deviation, σ, it is not expected that the option of using the variables sampling plans with known standard deviation will be generally available. However, if it is feasible to use such plans in particular circumstances, then the lot will be accepted when either:

$$\bar{x} \geq U - k\sigma$$

or $$\bar{x} \leq L + k\sigma$$

where:

$\bar{X}$ is the mean value of the criterion under consideration in the sample set and is obtained from a single analysis of blended bulked items. U, L and k are as defined for variables sampling with unknown standard deviation.

σ is the known standard deviation of the batch.

Values of k can be found in ISO 3951: 1981 (reference 3) if needed.

NOTES

Statistical probabilities not given in Instructions even though a recommended procedure as only one analysis required. To accept lot x must be less specification limit for characteristics if a maximum. But, σ is unlikely to be known beforehand and distribution of characteristic cannot be ascertained so individual item cut-off tolerances cannot be set (probably not important as σ is known).

4. Variables Sampling Criteria for Mean Quality

The following examples (A and B) on variables sampling for mean quality are included due to their widespread use. This document, however, does not elaborate the appropriate statistical testing procedures and properties therefore required for valid application. Users of these plans are cautioned against incorrect utilisation and are encouraged to appeal to appropriate references.

A. Individual Items Analysed

Procedure

1. Same sampling and analysis procedure as for 2 above.
2. But calculate only $\bar{X}$
3. Accept lot if $\bar{X}$ is less than a maximum permitted value of a characteristic (or more than a minimum value).

NOTES

Plan would be recommended for compositional characteristics. Statistical probabilities (e.g. number of items to be taken) not established in Instructions. Otherwise same advantages and disadvantage as (2).

B. Blended Bulk Sample Analysed.

Procedure:

1. Use same sampling and analysis procedure as for 3 above.
2. Calculate $\bar{X}$
3. Accept lot if $\bar{X}$ is less than a maximum permitted specification value of a characteristic in a lot (or more than a minimum value).

NOTES

Plan would be recommended for compositional characteristics. Statistical parameters (eg number of items to be taken) not established in Instructions but, simple to use and analyse. Distribution of characteristics in sampled items cannot be ascertained or an individual item cut-off tolerance established.

5. Other Plans

Other plans could be established whereby the above procedures are varied, eg a number of blended bulk samples could be produced, each consisting of a proportion of the items sampled. Each of these would be approached on a case-by-case basis.

6. Attribute Plan to Detect an Incidence in a Population

Procedure:

1. Use the same sampling diagram as for 1 above
2. Determine the incidence rate in terms of the percentage incidence in the population it is required to detect.
3. Find the minimum number of samples (n_o) necessary to detect an incidence with the preferred confidence indicated in Table 5.
4. There is no evidence of non-compliance if no incidents are found in the sample. Accept the lot if no incidents are found.

1. Sample size

Sample size to detect an incidence rate in a population is given in Table 5. The table shows sample sizes needed to be 90, 95, or 99 percent confident of observing an incident in the samples when the incidence rate in the population is at a given level. Choose the level to be detected and the Confidence to obtain the sample size using Table 5.

2. Operating Characteristics

The incidence rate corresponds to the limiting quality in a c=0 plan in Table 5. Table 6 shows operating characteristics for selected sample sizes.

NOTES

The probability of failing to detect an incident and accepting the lot depends upon the sample size and the actual incidence rate. Table 6 shows the probability of failing to detect an incident using different sample sizes from an "infinite" population with a specified proportion of violations.

7. Attribute Plan for Commodity Defects (AOL 6.5)

Procedure

Use the same sampling and analysis procedure as for 1 above.

1. Sample Size

Sample size will be found in Table 7 which was derived from Table 1. It can be used to select a plan or to match an AQL 6.5 plan to another international standard (such as ISO 2859)

1.1 To Select Plan

a. Find risks to be accommodated, associated with percent in lot which may be accepted, to find basic plan

b. If lot size is relatively constant, use basic plan on all lots

c. If lot sizes vary, find most common lot size across from basic plan, and use corresponding inspection level column to change plans by lot sizes shown

For example:

a. Suppose 5% non-conforming should be passed with high probability (95%) and 35% non-conforming should be passed with low probability (10%). Plan is n=13, c=2

b. If lot size is constant, use this plan only.

c. If lot size varies and most common lot size is 2000, use all plans according to inspection level S-3. Hence for lot sizes 10,000, ple plan n=20, c=3 would be used.

2. Fitting Existing Plan to another International Standard (e.g. ISO 2859)

a. If existing plan employs AQL = 6.5%, use plan n=13, c=2 as the basic plan, match the existing lot size range for this plan to those shown below as closely as possible and use the corresponding inspection level and plans from another international standard.

ISO 2859, Code E, 6.5% AQL Lot Size Ranges

ISO 2859	ISO 2859
Inspection Level	**Lot Size Range**
III	16-25
II	26-50
I	51-150
S4	151-500
S3	501-10000
S2	>10000

Example: The prepackaged foods plan has AQL=6.5% and for ints Inspection Level 1 shows n=13, c=2 with lot size 2000 for >4.5 kg. Therefore it would be reasonable to use the ISO 2859 sampling scheme with inspection level S-3 and 6.5% AQL if inspection to that standard is desired. Note also that sample size 13 for lot size 2000 appears above ISO inspection level S-3 in Table 1.

b. If existing plan has an AQL other than 6.5%, use Table 1 to accomplish this purpose by finding the ISO inspection level for the sample sizes used.

(i) Determine the AQL and LTPD with 95% and 10% probability of acceptance respectively for the existing plan

(ii) Locate the matching plan in Table 2 for attributed or Table 4 for variables data which has 95% and 10% probability of acceptance values close to those of the existing plan

(iii) Employing Table 1 for attributed or Table 3 for variables, find the samples size for the matching plan in the row indexed by the most common (or important) lot size for the application. Read the Inspection Level vertically from the sample size for use with ISO or other matching standards.

Example: Suppose an existing plan has an AQL of 6.5% and an LTPD of 35%. Inspection of Table 2 shows the plan n=13, c=2 has protection closest to these values. If the most common lot size is 2000, and is located in Table 1, the sample size 13 occurs above the level S-3 shown for ISO 2859. Therefore, the recommended matching designation for ISO 2859 is 6.5% AQL with Inspection Level S-3.

NOTE - Review of usage among Codex Committee Standards has shown an AQL of 6.5 percent to be utililised by most of the Committee Standards for commodity defects (such as in pre-packaged foods) which presently have sampling provisions. Accordingly this plan is presented as one that has passed the test of use within Codex for this purpose. It should be emphasized that the choice of specific AQL's and inspection levels appropriate to the application is essential and is the responsibility of the user(s) or Committee involved.

8.Tables

The following tables are given:

Table 1: sample sizes to be inspected from lots of different sizes and at different inspection levels for attribute acceptance sampling plans

Table 2: acceptance numbers (maximum number of defectives) permitted for different aql levels and probabilities and percentage of rejectable quality items in lots having 95%, 50 and 10% change of being accepted by attribute acceptance sampling plans.

Table 3 sample sizes to be inspected from lots of different sizes and at different inspection levels for variables acceptance sampling plans with unknown standard deviation

Table 4: sample sizes and acceptability at different aql levels and percentage of rejectable quality items in lots having 95%, 50% and 10% chance of being accepted for variables acceptance sampling plans with unknown standard deviation

Table 5: attribute plan to detect incidence rate in a population: sample sizes required to detect at least one violation with predefined probabilities (i.e. 90, 95 and 99 per cent) in a population having a known violation incidence rate

Table 6: probability of acceptance (%) for attribute plan to detect incidence rate in population

Table 7: attribute plan for commodity defects AQL = 6.5 and various inspection levels

TABLE 1: SAMPLE SIZES TO BE INSPECTED FROM LOTS OF DIFFERENT SIZES AND AT DIFFERENT INSPECTION LEVELS FOR ATTRIBUTE ACCEPTANCE SAMPLING PLANS

Size of Lot (Number of Items)	**Number of Items to be Inspected**				
	Inspection Level*				
	1	**2**	**3**	**4**	**5**
≤ 15	2	2	2	3	5
16-25	3	3	3	5	8
26-50	3	5	5	8	13
51-90	5	5	5	13	20
91-150	5	8	8	20	32
151-280	8	13	13	32	50
281-500	8	13	20	50	80
501-1200	13	20	32	80	125
1201-3200	13	32	50	125	200
3201-10000	20	32	80	200	315
10001-35000	20	50	125	315	500
≥35000	32	80	200	500	800

ISO Inspection Level	**S-3**	**S-4**	**I**	**II**	**III**

Selected from ISO 2859: 1974 (reference 2)

* These correspond to inspection levels S-3, S-4, I, II and III in the ISO Standard.

TABLE 2: ACCEPTANCE NUMBERS (MAXIMUM NUMBER OF DEFECTIVES) PERMITTED FOR DIFFERENT AQL LEVELS AND PROBABILITIES AND PERCENTAGE OF REJECTABLE QUALITY ITEMS IN LOTS HAVING 95%, 50 AND 10% CHANCE OF BEING ACCEPTED BY ATTRIBUTE ACCEPTANCE SAMPLING PLANS.

Sample Size	Acceptance Number (c)	AQL of Plan (%)	Percentage of Defectives in a lot which may be Accepted		
			95%	50%	10%
			Of the time		
2	0	6.5	2.5	29	68
3	0	4.0	1.7	21	54
5	0	2.5	1.0	13	37
	1	10.0	7.6	31	58
8	0	1.5	0.6	8.3	25
	1	6.5	4.6	20	41
	2	10.0	11	32	54
13	0	1.0	0.4	5.2	16
	1	4.0	2.8	13	27
	2	6.5	6.6	20	36
	3	10.0	11	28	44
20	0	0.65	0.3	3.4	11
	1	2.5	1.8	8.2	18
	2	4.0	4.2	13	24
	3	6.5	7.1	18	30
	5	10.0	14	28	42
32	1	1.5	1.1	5.2	12
	2	2.5	2.6	8.3	16
	3	4.0	4.4	11	20
	5	6.5	8.5	18	27
	7	10.0	13.1	24	34
50	0	0.25	0.1	1.4	4.5
	1	1.0	0.7	3.3	7.6
	3	2.5	2.8	7.3	13
	5	4.0	5.3	11	18
	7	6.5	8.2	15	22
	10	10.0	13	21	29

Note: The 95% column represents the corresponding AQL's for a Producer's risk of 5%

TABLE 2 (continued)

Sample Size	Acceptance Number (c)	AQL of Plan (%)	Percentage of Defectives in a lot which may be Accepted		
			95%	50%	10%
			Of the time		
80	1	0.65	0.4	2.1	4.8
	2	1	1.0	3.3	6.5
	5	2.5	3.3	7.1	11
	7	4	5.1	9.6	14
	10	6.5	7.9	13	19
	14	10	13	18	24
125	0	0.1	0.04	0.6	1.8
	2	0.65	0.7	2.1	4.3
	3	1	1.1	2.9	5.4
	7	2.5	3.2	6.1	9.4
	10	4	4.9	8.5	12
	14	6.5	7.4	12	16
	21	10	12	17	23
200	1	0.25	0.2	0.8	2.0
	3	0.65	0.7	1.8	3.3
	5	1	1.3	2.8	4.6
	10	2.5	3.1	5.3	7.7
	14	4.0	4.6	7.3	10
	21	6.5	7.5	11	14
315	2	0.25	0.3	0.5	1.7
	5	0.65	0.8	1.8	2.9
	7	1	1.3	2.4	3.7
	14	2.5	2.9	4.7	6.4
	21	4.0	4.7	6.9	9.0
500	1	0.1	0.1	0.3	0.8
	3	0.25	0.3	0.7	1.3
	7	0.65	0.8	1.5	2.4
	10	1	1.2	2.1	3.1
	21	2.5	3.0	4.3	5.6
800	2	0.1	0.1	0.3	0.7
	5	0.25	0.3	0.7	1.2
	10	0.65	0.8	1.3	1.9
	14	1	1.2	1.8	2.5

TABLE 3 SAMPLE SIZES TO BE INSPECTED FROM LOTS OF DIFFERENT SIZES AND AT DIFFERENT INSPECTION LEVELS FOR VARIABLES ACCEPTANCE SAMPLING PLANS WITH UNKNOWN STANDARD DEVIATION

Size of Lot (Number of Items)	**Number of Items to be Inspected Inspection Level**				
	1	**2**	**3**	**4**	**5**
≤ 15	3	3	3	3	5
16-25	3	3	3	4	7
26-50	3	3	4	5	10
51-90	3	3	5	7	15
91-150	3	4	7	10	20
151-280	3	5	10	15	25
281-400	4	7	15	25	35
401-500	4	7	15	25	35
501-1200	5	10	20	35	50
1201-3200	7	15	25	50	75
3201-10000	10	20	35	75	100
10001-35000	15	25	50	100	150
≥35000	20	35	75	150	200
ISO Inspection Level	S-3	S-4	I	II	III

Selected from ISO 3951: 1981 (reference 3)

TABLE 4: SAMPLE SIZES AND ACCEPTABILITY AT DIFFERENT AQL LEVELS AND PERCENTAGE OF REJECTABLE QUALITY ITEMS IN LOTS HAVING 95%, 50% AND 10% CHANCE OF BEING ACCEPTED FOR VARIABLES ACCEPTANCE SAMPLING PLANS WITH UNKNOWN STANDARD DEVIATION

Sample Size (n)	Acceptance Constant (k)	AQL of Plan (%)	Percentage of Defectives in a lot which may be Accepted		
			95%	50%	10%
			Of the time		
3	1.12	2.5	109	17	49
	0.968	4.0	1.9	20	53
	0.765	6.5	3.5	25	57
	0.566	10.0	6.0	31	62
4	1.45	1.0	0.4	9.5	35
	1.17	2.5	1.3	14	41
	1.01	4.0	2.3	18	45
	0.814	6.5	4.1	23	50
	0.617	10.0	6.9	29	56
5	1.65	0.65	0.3	6.3	36
	1.53	1.0	0.5	7.8	28
	1.24	2.5	1.4	12	35
	1.07	4.0	2.4	16	39
	0.874	6.5	4.3	21	45
	0.675	10.0	7.1	26	50
7	2.00	0.25	0.1	2.1	9.4
	1.75	0.65	0.4	3.8	13
	1.62	1.0	0.6	4.8	15
	1.33	2.5	1.7	8.6	21
	1.15	4.0	2.8	12	26
	0.955	6.5	4.6	18	37
	0.755	10.0	7.5	24	43
10	2.11	0.25	0.1	2.1	9.4
	1.84	0.65	0.4	3.8	13
	1.72	1.0	0.6	4.8	15
	1.41	2.5	1.7	8.6	21
	1.23	4.0	2.8	12	26
	1.03	6.5	4.6	18	37
	0.828	10.0	7.5	24	43
15	2.42	0.1	0.06	0.94	0.3
	2.20	0.25	0.15	1.6	6.1
	1.91	0.65	0.45	3.1	9.4
	1.79	1.0	0.7	4.0	11
	1.47	2.5	1.9	7.5	17
	1.30	4.0	3.1	10	20
	1.09	6.5	5.3	14	26
	0.886	10.0	8.4	19	32

Table 4 continued...

Sample Size (n)	Acceptance Constant (k)	AQL of Plan (%)	Percentage of Defectives in a lot which may be Accepted		
			95%	50%	10%
			Of the time		
20	2.47	0.1	0.07	0.8	3.1
	2.24	0.25	0.2	1.4	4.7
	1.96	0.65	0.5	2.7	7.5
	1.82	1.0	0.8	3.7	9.2
	1.51	2.5	2.1	6.9	14
	1.33	4.0	3.4	9.5	18
	1.12	6.5	5.7	13	23
	0.917	10.0	8.9	18	29
25	2.50	0.1	0.08	0.7	2.6
	2.26	0.25	0.2	1.3	4.0
	1.98	0.65	0.6	2.5	6.5
	1.85	1.0	0.9	3.4	8.0
	1.53	2.5	2.2	6.5	13
	1.35	4.0	3.6	9.1	16
	1.14	6.5	6.0	13	21
	0.936	10.0	9.3	18	27
35	2.54	0.1	0.09	0.6	1.9
	2.31	0.25	0.2	1.1	3.0
	2.03	0.65	0.6	2.2	5.1
	1.89	1.0	0.9	3.1	6.5
	1.57	2.5	2.4	6.0	11
	1.39	4.0	3.8	8.4	14
	1.18	6.5	6.2	12	19
	0.969	10.0	9.7	17	24
50	2.60	0.1	0.10	0.5	1.4
	2.35	0.25	0.3	1.0	2.4
	2.08	0.65	0.6	1.9	4.0
	1.93	1.0	1.0	2.8	5.3
	1.61	2.5	2.5	5.5	9.2
	1.42	4.0	4.0	7.9	12
	1.21	6.5	6.5	11	17
	1.00	10.0	10.0	16	22

Table 4 Continued...

Sample Size (n)	Acceptance Constant (k)	AQL of Plan (%)	Percentage of Defectives in a lot which may be Accepted		
			95%	50%	10%
			Of the time		
75	2.66	0.1	0.1	0.1	1.0
	2.41	0.25	0.3	0.8	1.7
	2.12	0.65	0.4	1.7	3.2
	1.98	1.0	1.1	2.4	4.3
	1.65	2.5	2.6	5.0	7.8
	1.46	4.0	4.2	7.3	11
	1.24	6.5	6.8	11	15
	1.03	10.0	10	15	20
100	2.69	.01	0.1	0.4	0.8
	2.43	0.25	0.3	0.8	1.5
	2.14	0.65	0.4	1.6	2.9
	2.00	1.0	1.1	2.3	3.8
	1.67	2.5	2.7	4.8	7.1
	1.48	4.0	4.3	7.0	9.8
	1.26	6.5	7.0	10	14
	1.05	10.0	11	15	19
150	2.73	0.1	0.1	0.3	0.6
	2.47	0.25	0.3	0.7	1.2
	2.18	0.65	0.8	1.5	2.4
	2.03	1.0	1.2	2.1	3.3
	1.70	2.5	2.8	4.5	6.3
	1.51	4.0	4.4	6.6	8.8
	1.29	6.5	7.1	9.9	13
	1.07	10	11	14	17
200	2.73	0.1	0.1	0.3	0.6
	2.47	0.25	0.3	0.7	1.1
	2.18	0.65	0.8	1.5	2.2
	2.07	1.0	1.3	2.1	3.0
	1.70	2.5	3.0	4.5	6.0
	1.51	4.0	4.7	6.6	8.5
	1.29	6.5	7.4	9.9	12
	1.07	10.0	11	14	17

TABLE 5: ATTRIBUTE PLAN TO DETECT INCIDENCE RATE IN A POPULATION

SAMPLE SIZES REQUIRED TO DETECT AT LEAST ONE VIOLATION WITH PREDEFINED PROBABILITIES (I.E 90, 95 AND 99 PERCENT) IN A POPULATION HAVING A KNOWN VIOLATION INCIDENCE RATE

Violence Incidence (%) in a Population	**Sample Size (n_0) required to detect a violation with a confidence of**		
	90%	**95%**	**99%**
35	6	7	11
30	7	9	13
25	9	11	17
20	11	14	21
15	15	19	29
10	22	29	44
5	45	59	90
1	230	299	459
.5	460	598	919
.1	2302	2995	4063
100p**	2.302/p	2.996/p	4.605/p

*The number of primary samples does not depend on population size, except when the number of samples shown in the table is greater than about 10% of the population size. The following formula can be used to adjust the table values for the minimum number of primary samples (n_0)a nd compute the required minimum number of primary samples (n) for a given lot size (N):[1]

$$n = \frac{n_0}{1 + (n_0 - 1)/N}$$

** To use this row for percent defective 100p, multiply the values shown by p.

TO USE THIS TABLE

1. Sample Size

Sample size will be found in Table 7 which was derived from Table 1. It can be used to select a plan or to match an AQL 6.5 plan to another international standard (such as ISO 2859).

1.1 To Select Plan

a) Find risks to be accommodated, associated with percent in a lot which may be accepted, to find basic plan.

b) If lot size is relatively constant, use basic plan on all lots.

c) If lot sizes vary, find most common lot size across from basic plan, and use correspondoing inspection level column to change plans by lot sizes shown.

For Example:

a) Suppose 5% non-conforming should be passed with high probability (95%) and 35% non-conforming should be passed with low probability (10%). Plan is n = 13, c = 2.

b) If lot size is constant, use this plan only.

c) If lot size varies and most common lot size is 2000, use all plans according to inspection level S-3. Hence for lot size 10,000, the plan n = 20, c = 3 would be used.

TABLE 6: PROBABILITY OF ACCEPTANCE (%) FOR ATTRIBUTE PLAN TO DETECT INCIDENCE RATE IN POPULATION

Prevalence (%)	**Sample size**									
	5	10	25	50	75	100	200	250	500	1000
1	0.951	0.904	0.779	0.605	0.471	0.366	0.134	0.081	0.007	0.000
2	0.904	0.817	0.603	0.364	0.220	0.133	0.018	0.006	0.000	
3	0.859	0.737	0.467	0.218	0.102	0.048	0.002	0.000		
4	0.815	0.665	0.360	0.130	0.047	0.017	0.000			
5	0.774	0.599	0.277	0.077	0.021	0.006				
6	0.734	0.539	0.213	0.045	0.010	0.002				
7	0.696	0.484	0.163	0.027	0.004	0.001				
8	0.659	0.434	0.124	0.015	0.002	0.000				
9	0.624	0.389	0.095	0.009	0.001					
10	0.590	0.349	0.072	0.005	0.000					
12	0.528	0.279	0.041	0.002						
14	0.470	0.221	0.023	0.001						
16	0.418	0.175	0.013	0.000						
18	0.371	0.137	0.007							
20	0.328	0.107	0.004							
24	0.254	0.064	0.001							
28	0.193	0.037	0.000							
32	0.145	0.021								
36	0.107	0.012								
40	0.078	0.006								
50	0.031	0.001								
60	0.010	0.000								

TABLE 7: ATTRIBUTE PLAN FOR COMMODITY DEFECTS AQL = 6.5 AND VARIOUS INSPECTION LEVELS

% in Lot which may be accepted 95% of the time	% in Lot which may be accepted 10% of the time	ISO 2859 Plan Code	Sample Size	Acc No (c)	Inspection Level, Maximum Lot Size						
					S-1	**S-2**	**S-3**	**S-4**	**I I**	**II**	
2.5	68	A,B	2	0	500	150	50	25	25	15	8
4.6	41	C,D	8	1	>500	3500	500	150	150	50	25
6.6	36	E	13	2	↓	>35000	3200	500	280	90	50
7.1	30	F	20	3	↓	↓	3500	1200	500	150	90
8.5	27	G	32	5	↓	↓	500000	10000	1200	280	150
8.2	22	H	50	7	↓	↓	>500000	35000	3200	500	280
7.9	19	J	80	10	↓	↓	↓	500000	10000	1200	500
7.4	16	K	125	14	↓	↓	↓	>500000	35000	3200	1200
7.5	14	L	200	21	↓	↓	↓	↓	150000	1000	3200
↓	↓	M	↓	↓	↓	↓	↓	↓	500000	35000	10000
		N			↓	↓	↓	↓	>500000	150000	35000
		P			↓	↓	↓	↓	↓	500000	150000
		Q			↓	↓	↓	↓	↓	>500000	500000
		R			↓	↓	↓	↓	↓	↓	>500000
					↓	↓	↓	↓	↓	↓	↓