SAMPLING IN CODEX STANDARDS – HOW SHOULD IT BE TREATED?

Background note:

This paper was prepared by Roger Wood, Chairman of ICUMSA Subject 3 Group dealing with Method Format, Collaborative Testing and Statistical Treatment of Data and will be discussed at the next Inter-Agency Meeting, to be held 2nd March, 2013. Comments made at that Meeting will be summarised and made available to participants at the forthcoming Session of the Codex Committee on Methods of Analysis and Sampling.

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A DISCUSSION PAPER

INTRODUCTION and BACKGROUND

In the Report of the last (33rd) Session of CCMAS it is stated at paragraph 89: "The Committee agreed to ask IAM to provide a short discussion paper on sampling issues for consideration at the next session taking into consideration the information in CRD 12."

This paper is an attempt to meet that request.

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). Other definitions are also available, such as that given in VIM3.

Sampling in the Measurement Process

Sampling has 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 therefore 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, the next question to address is 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 has been to designate this optimal value of uncertainty, as the point that minimises the overall financial loss to the user of the measurements. The next step in this approach is to find procedures to modify the uncertainty of a measurement system, in order to achieve this optimal value, if the actual value is initially sub-optimal.

Another is 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.

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 batch composition, 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; however neither a consensus method nor routine implementation is forthcoming at this time.

History

"Methods of sampling" have had a long and troubled history within Codex. It may be summarised as follows:

1986: The principles for the establishment or selection of Codex sampling procedures were first adopted by the Commission. These lay down:
The purpose Of Codex methods of sampling
Types of Sampling Plans and Procedures:
- Sampling Plans for Commodity Defects:
- Sampling Plans for Net Contents:
- Sampling Plans for Compositional Criteria:
- Specific Sampling Plans for Health-related Properties
General Instructions for the Selection of Methods of Sampling

1988: Instructions on Codex sampling procedures. These covered:

Aspects of sampling and acceptance procedures
Types of sampling plans
Procedure to be followed by Codex Commodity Committee when developing a sampling plan
Diagrammatic representation of possible Codex sampling plans
Description of and formulae to be used in acceptance sampling plans adopted by Codex
Net contents
Selection of values of mathematical parameters for the operation of Codex sampling plans

2004 General Guidelines on Sampling (published as CAC/GL 50-2004). These covered

Main notions of sampling
The selection of sampling plans for single or isolated lots moving in international trade
The selection of sampling plans for a continuous series of lots from a single source
The selection of sampling plans for the inspection by variables of bulk materials: known standard deviation

2007: Amendments to the principles for the establishment or selection of codex sampling procedures as published in the Codex Procedural Manual.

The Codex Alimentarius Commission, through the Codex Committee on Methods and Sampling, has adopted "Principles for the Establishment or Selection of Codex Sampling Procedures" and has also developed general guidance on sampling. Some concern has been expressed about the issue of sampling and the practical application of these principles, and indeed how they help Codex Committees develop sampling plans. It is considered that the variability inherent in sampling from a lot is not well understood by many. All too frequently Codex Committees simply refer to the Codex Guidelines on Sampling not appreciating that they have to select from those Guidelines and not just make reference to them. The Principles are given in Appendix I of this discussion document.

It is now appropriate to re-visit the Guidelines and discuss how sampling should be next developed within Codex.

In essence there are three ways of doing this:

1. To carry out acceptance sampling as being indicated by the general Guidelines on Sampling. It is important to recognise just how variable acceptance sampling plans really are.

Acceptance plans are simply explained in the introduction to the 1988 Codex document "Instructions on Codex Sampling Procedures" which were first prepared in 1988 and then re-issued as a CL 1994 (see Appendix II of this discussion paper. The original document is available. An example of this may be readily appreciated by considering the table 2 given in the "Instructions". Here the 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 are given. It is the 10% chance column which is of particular interest and illustrates the danger (weakness) of these plans to the consumer when the number of items in a sample are reduced. Similar tables of values are available for variable plans with known and unknown standard deviations.

The problem here is defining the AQL for different analytes within a Codex Standard, and this then immediately assumes the proportion defective which is going to be acceptable.

2. To carry out the uncertainty of sampling approach. However, this approach has had a mixed reception in the food sector, particularly within Codex, even though it clearly identifies the extent of variability that exists when sampling a "lot". The values of sampling uncertainty which have been previously reported to CCMAS are given in the Table headed "Magnitude of Sampling Uncertainty" (see Appendix III of this document). This table also shows the analytical uncertainties.

3. To define a sampling procedure and ignore what the actual variability is. This is what effectively happens in many situations, e.g. aflatoxins where an amount (usually 30 kg) is taken from a lot (of many tonnes). Any statistical relationship between the sample and the lot from where it is taken is ignored. It is a (the) pragmatic approach. So often the concept of taking a "representative sample" is used when this means that the uncertainty from sampling is ignored. Clearly that is administratively convenient but scientifically incorrect.

DISCUSSION

The way forward here is difficult to determine. It is possible to:

a. Acceptance Sampling

Maintain the present approach defined by the Codex Sampling Principles. This 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.

b. Estimate total uncertainty

Quantify the total uncertainty in the measurement process, including that from both analysis and sampling and assessing 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.

c. Representative Uncertainty

Ignoring all aspects of sampling uncertainty and defined a practical plan with little scientific basis..

d. Auto-Control

Consider a radically different approach, i.e. verifying the results obtained from continuous food production. This approach, called here "auto-control" is described in the Appendix IV.

It is apparent different Codex Committees take different approaches to sampling, leading to potential confusion and uncertainty amongst users and indeed developers, of Codex Standards.

It must be appreciated that all of the above approaches are directed towards consideration of a defined characteristic in a Standard and are not applicable to adventitious or deliberate adulteration of a product.

RECOMMENDATIONS

This brief paper illustrates some of the issues arising in a very complex subject.

It is recommended that these issues are brought to Codex Committees in a form that is easily appreciated by non-specialists who have to define the characteristics within any Codex Standard.

APPENDIX I: 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 be written 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.

APPENDIX II: EXTRACT FROM THE 1988 INSTRUCTIONS ON CODEX SAMPLING PROCEDURES

The 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.

CONTENTS

Section

APPENDICES

1. INTRODUCTION AND GENERAL BACKGROUND

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 III, Codex Alimentarius Commission, Procedural Manual, Sixth 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 Selection of Codex Sampling Procedures" (see paras 54-58 and Appendix IV of ALINORM 83/23 and the Sixth Edition of the Procedural Manual of the CAC). These General Principles have now been adopted by the Codex Alimentarius Commission. Both these General Principles are given in Appendix I of these Instructions for easy reference.

It will be seen that there are many similarities between the two aspects 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, critical 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[1]. 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.

These Instructions on Sampling are intended to ensure that the General principles are fully understood and correctly applied in the selection of Codex sampling procedures. It is also intended that these Instructions 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**.**

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 attached 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 clearly 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 typically 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 Commodity 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.

TABLES

One table is extracted from the Instructions and given on the following page. It will be very useful when considering the CCMAS Endorsement paper CX/MAS 13/34/3 and attempts to demonstrate just how “variable” sampling is!

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.

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
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

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

The table continues to give values for sample sizes of 200, 315,500 and 800.

APPENDIX III: MAGNITUDE OF SAMPLING UNCERTAINTY

Work has been carried out to estimate the sampling uncertainties which are likely to arise in the food sector. These are given in the following table:

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(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 (glasshouse)	Nitrate	mg kg^{-1}	4408	16.4	14.48	7.62
			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 (tinned)	Tin (Sn)	mg kg^{-1}	6.455	79.44	75.17	25.69
	Tin (Sn)	mg kg^{-1}	74.26	20.55	19.66	6.01

Butter (fresh)	Moisture	% m/m	15.41	0.78	0.67	0.39
			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

APPENDIX IV: 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 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, 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 with official control procedures when unsatisfactory sample results are found.
- Prevents disputes over differences between official analytical results and in-house results.
- 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.

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

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.

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 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%)