codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3 **CX/MAS 01/3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Twenty-third Session
Budapest, Hungary, 26 February – 2 March 2001

PROPOSED DRAFT GENERAL GUIDELINES ON SAMPLING
(At Step 3 of the Procedure)

Background

The Committee on Methods of Analysis and Sampling undertook the development of general guidelines for sampling at its 19th Session (1994), with the understanding that they were intended to replace all current texts on sampling. The 22nd Session of the Committee considered a revised draft of the Proposed Draft General Guidelines on Sampling and decided to defer detailed discussion on the text due to its complexity.

The Committee agreed that the text should be revised to make it easier, simpler and more used friendly. It reiterated its decision of the last session that the text should contain worked examples for specific cases to facilitate its use. The Delegation of Hungary offered to provide some of these examples. It was pointed out that experts in specific commodities in the countries participating in the drafting could also contribute. The Committee agreed that specific attention should be given to matters relating to "heterogeneity" in bulk materials, and that further information should be sought from Codex commodity committees on the acceptance of the statistical approach to sampling (ALINORM 99/23, paras. 9-13).

The Committee returned the Proposed Draft to Step 3 for redrafting by France in collaboration with Australia, Netherlands, United Kingdom, United States and IDF, including the preparation of an explanatory note, and consideration at the next session.

The Proposed Draft General Guidelines, as redrafted by France in collaboration with other countries as indicated above, is hereby circulated for comments at Step 3. Governments and international organizations wishing to submit comments should do so in writing (if possible by Email) to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, with a copy to Dr. Mária Váradi, Central Food Research Institute (KÉKI), Herman Ottó út 15, H-1022 Budapest, Fax : +361 212 9853 or 361 355 8928, Email : m.varadi@mail.cfri.hu, **before 15 January 2000**

PROPOSED DRAFT GENERAL GUIDELINES ON SAMPLING
(At Step 3 of the Procedure)

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SECTION 1. PURPOSE AND SCOPE OF CODEX SAMPLING GUIDELINES

1.1 PURPOSE

Sampling plans are required which ensure that fair and valid procedures are used when food is being tested for compliance with a particular Codex commodity standard.

Since numerous, yet often complex, sampling plans are available it is the purpose of these guidelines to help those responsible for sampling to select sampling plans for statistical inspection under specifications laid down by Codex standards.

This document presents the elementary principles of statistical inspection at reception[1] by the sampling of individualizable goods (a pre-packaged item, the content of a recipient or a spoon plunged into bulk). It recommends single sampling plans[2]:

- **by attributes for the statistical inspection of the percentage of nonconforming items.** This is a method of evaluating the quality of a lot which, for each of the increments forming a sample, consists in recording the presence or absence of a given qualitative characteristic known as the attribute, then in counting the number of increments having this attribute. The inspected lot acceptance rule laid down by the sampling plan is based on a maximum number of increments having the defined attribute; this maximum number is also set by the sampling plan (cf. section 2.4.3.1)
- **by variables for the statistical inspection of the percentage of nonconforming items**. This is a method of evaluating quality which consists in measuring a quantitative characteristic of each of the increments forming a collected sample; the inspected lot acceptance rule laid down by the sampling plan is based on the results of measurements made on each increment forming the sample. **This method assumes that the inspected characteristic is measurable and that the numeric values of this characteristic are distributed according to the Laplace-Gauss law of probability, (so-called Normal law)** (cf section 2.4.3.2). If it is known that the distribution is not normal, a sampling plan by attribute is to be applied.
- **for microbiological inspections,**
- **in some circumstances, other sampling plans may have to be developed, e.g. a spiked contamination by aflatoxins.**

1.2 DOCUMENT TARGET AUDIENCE

These recommendations are above all aimed at Codex Commodity Committees which select from the plans recommended in sections 3, 4, and 5 those which at the time of the drafting of a commodity standard appear to them best suited for the inspection to be made. These recommendations can also be used, if applicable, by governments in the event of international trade disputes.

1.3 SCOPE OF THE GUIDELINES

The following table 1 summarises the situations covered by Codex guidelines and those which are excluded. It also gives, where applicable, useful international references for some of the situations not covered by these Codex guidelines. As they are deemed more complex, double, multiple and sequential sampling plans for the inspection of percent nonconforming, as well as sampling plans for the inspection on reception of an average content, are to be addressed later if necessary. These tables differ from those of section 6 whose aim is to provide practical help when selecting a sampling plan.

[1] The process controls are excluded from the scope of this document. If the product Committees wish to deal with them, they could ask CCMAS to prepare it.

[2] Double, multiple and sequential sampling plans are to be addressed later, if necessary, as they are deemed too complex.

TABLE 1

Inspection situations	**Sampling of individualizable, non homogeneous, bulk commodities**	**Single sampling of individualizable, homogeneous, bulk commodities** **for statistical inspection on reception by variables of percent nonconforming**	**Single sampling of individualizable commodities** **for statistical inspection on reception by attributes of percent nonconforming (refer to 2.4.2 for the particular case of zero acceptance number)**	**Single sampling of individualizable commodities** **for statistical inspection on reception by variables of percent nonconforming**	**Single sampling of individualizable commodities** **for statistical inspection on reception of an average content[3]** **Example: sodium content of a dietary food**
Inspection of isolated lots: **Quantitative criteria**	not addressed Example: inspection of aflatoxin content of a cargo of cereals (i.e. sporadic contamination)	section 5.1 Example: water content of a tank of milk	section 2.4.3.4, section 3.1, Examples: fat content of a skimmed milk, residual lead content in apples	excluded, the isolated lots method applies only to attributes plans Examples: fat content of a skimmed milk, sodium content of a dietary cheese	to be addressed later see also ISO 2854-1974, 3494-1976
Inspection of isolated lots: **Qualitative criteria**	not addressed	excluded because a qualitative variable cannot be measured	section 3.1 Example: inspection of the aspect of a piece of fruit, of a can	Excluded because a qualitative variable cannot be measured	excluded because a qualitative variable cannot be measured
Inspection of continuing lots **Quantitative criteria**	not addressed	section 5.1 Example: water content of a tank of milk	section 2.4.3.4, section 4.2 Examples: fat content of a skimmed milk, residual lead content in apples	section 4.3 Examples: fat content of a skimmed milk, sodium content of a dietary cheese	to be addressed later Example: sodium content of a dietary food see also ISO 2854-1974, 3494-1976
Inspection of continuing lots: **Qualitative criteria**	not addressed	excluded because a qualitative variable cannot be measured	section 4.2 Example: inspection of the aspect of a piece of fruit, of a can	Excluded because a qualitative variable cannot be measured	excluded because a qualitative variable cannot be measured

Inspection situations	**Sampling for microbiological inspection**	**Sampling for inspection of nominal quantity (net content or volume content)**	**Double, multiple, sequential sampling of individualizable commodities** **for statistical inspection on reception,** **by attributes or by variables, of percent nonconforming** **... Example: fat content of a skimmed milk**	**Other sampling situations: ...** **Sampling for food safety inspection:** **- Inspection of residual content of benzopyrene in foods, or of sulphonamide residue in milk[4]** **- Punctual sampling[5]** **– Sampling for statistical process control**
Inspection of isolated lots:	section 3.2	to be addressed later if necessary	to be addressed later if necessary	excluded

[3] This case is to be addressed later owing to the importance for the quality of foodstuffs of the inspection of an average content, which is very often specified in CODEX standards. It may however be addressed indirectly by an attributes inspection insofar as each increment can be termed conforming or nonconforming depending on whether the average content of the inspected variable conforms or not to the qualitative specification.

[4] The arrangements of such inspection, which depend on the circumstances of its implementation, must take into account the assessment of the risk incurred.

[5] This is an empirical sampling which in certain cases (i.e. presence of contaminants hazardous for health, could be dealt later on. For the time being, any lot containing the contaminant should be refused.

Quantitative criteria	ex : mesophilic aerobic microorganims in unheated vegetables See also ICMSF standards		See also ISO 2859, 8422, 8423	
Inspection of isolated lots: **Qualitative criteria**	section 3.2 ex : *Salmonella* in unheated vegetables See also ICMSF standards	excluded because a qualitative variable cannot be measured	to be addressed later if necessary for attributes plans; excluded for variables plans because a qualitative variable cannot be measured	excluded
Inspection of continuing lots **Quantitative criteria**	section 3.2 ex : mesophilic aerobic microorganims in unheated vegetables See also ICMSF standards	to be addressed later if necessary	to be addressed later if necessary See also ISO 2859, 8422, 8423	excluded
Inspection of continuing lots: **Qualitative criteria**	section 3.2 ex : *Salmonella* in unheated vegetables See also ICMSF standards	excluded because a qualitative variable cannot be measured	to be addressed later if necessary for attributes plans; excluded for variables plans because a qualitative variable cannot be measured	excluded

1.4 Relationship with the ISO and ANSI Standards

In the cases of control situations dealt with by this document, the sampling shall only follow the rules of the sampling plans of this document, even if this document refers to the following ISO or ANSI Standards for the details of the scientific and statistical background.

In the cases of control situations not dealt with by this document, and if they are dealt with by an ISO Standard (see below), the product Committee or the governments should refer to them, and define how to use them.

The a.m. ISO and ANSI Standards are the following :

- ISO 2854 : 1976(E) : Statistical interpretation of data – Techniques of estimation and tests relating to means and variances
- ISO 2859-0:1995(E)): Sampling procedures for inspection by attributes - Part 0: Introduction to the ISO 2859 attribute sampling system
- ISO 2859-1:1989(E): Sampling procedures for inspection by attributes - Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection
- ISO 2859-2-1985(E): Sampling procedures for inspection by attributes - Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection
- ISO 3494:1976 : Statistical interpretation of data – Power of tests relating to means and variances
- ISO 3951:1989(E): Sampling procedures and charts for inspection by variables for percent nonconforming
- ISO 7002:1986 (E) : Agricultural food products - Layout for a standard method of sampling a lot,
- ISO 8423:1991(E): Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation)
- ISO 8422:1991(E): Sequential sampling plans for inspection by attributes
- ISO/TR 8550:1994(E)): Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots
- ISO/CD 10725-2.3: Acceptance sampling plans and procedures for the inspection of bulk material Part 2: Known standard deviation (Draft standard)
- ANSI/EIA-585-1991: Zero acceptance number sampling procedures and tables for inspection by attributes of isolated lots

The standards listed above were valid at the time of publication of these guidelines. However, since all standards are subject to revision, parties to agreements based upon these guidelines should ensure that the

most recent editions of the standards are always applied.

Section 2 : Vocabulary and main notions of sampling

2.1 Introduction

2.1.1 Presentation of the section

This section presents:

- the rationale and the procedure to be followed before sampling in a lot and selecting a sampling plan (section 2.1.2);
- the vocabulary and the main notions used in sampling (section 2.2), particularly **the principle of the operating characteristic curve of a sampling plan and the related notions of acceptable quality (**quality goal which the manufacturer aims to achieve) **and the limiting quality level (**the worst quality acceptable to the consumer), **(section 2.2.5)**. **The operating characteristic curve of a sampling plan is the curve which relates the rate of nonconforming items in lots and the probability of acceptance of these lots upon inspection.** This notion is essential for risk assessment prior to selecting a plan;
- sampling techniques, which are methods to collect and form the sample to be analysed (section 2.3);
- the types of sampling plans of an inspected lot which lay down the rule for reaching a decision on the basis of the results obtained on samples taken from that lot, in other words the acceptance or refusal of the lot after inspection (section 2.4);
- the principle of the inspection by single sampling plans by attributes (section 2.4.3.1) and by single sampling plans by variables (section 2.4.3.2) of percent nonconforming is presented and illustrated by the corresponding and compared operating characteristic curves (section 2.4.3.3);
- the selection of an attributes plan or a variables plan is illustrated by a diagram of the decision to be taken in terms of the inspection situations encountered (section 2.4.3.4);
- a table summarises the comparative advantages and disadvantages of an attributes plan and a variables plan (section 2.4.3.5).

2.1.2 General

All sampling procedures involve the selection of a sample (or samples) from a lot, the inspection or analysis of the sample, and the classification of the lot (as 'acceptable' or 'not acceptable') based upon the result of the inspection or analysis of the sample.

An acceptance *sampling plan* is a set of rules by which a lot is to be inspected and classified. The plan will stipulate the number of items, randomly selected from the lot under inspection, which will comprise the sample. A sampling procedure which involves '*switching*' (see Section 2.2.10) from one sampling plan to another is referred to as a '*sampling scheme*'. A collection of sampling plans and sampling schemes constitutes a '*sampling system*'.

The appropriate *Codex Commodity Committee* should maintain the closest possible relations with all interested organisations working on methods of analysis and sampling; and should keep under constant review all methods of sampling and analysis published in the *Codex Alimentarius*. Before elaborating any sampling plan, or before any plan is endorsed by the *Codex Committee on Methods of Analysis and Sampling*, the Commodity Committee should also indicate the following:

- The basis on which the criteria in the Codex Commodity standards have been drawn up, for example;
    - whether on the basis that *every item* in a lot, or *a specified high proportion of items*, 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
- Whether there is to be any differentiation in the relative importance of the criteria in the standards. If so, the appropriate statistical parameter to be applied to each criterion should be indicated

Instructions on the procedure for implementing the sampling plan should indicate the following:

- The measures necessary in order to ensure that the sample taken is *representative* of the consignment or of the lot. (If a consignment consists of several well-defined lots, samples should be collected that are representative of the individual lots.)
- The samples shall be taken randomly, since they are more likely to reflect the quality of the lot, but information from a sample .may still not be identical with that from the whole lot (it is the sampling error).
- The *size and number of individual items* forming the sample taken from the lot or consignment
- The procedures to be adopted for *collecting, handling* and *recording* the sample(s)

The following issues should also be addressed when selecting a sampling procedure:

- The nature of the characteristic(s) to be controlled (See Section 2.2.1)
- The distribution of the characteristic(s) in the population to be sampled
- The relationship between the characteristic(s) and the quality specification of the product under examination
- The destructive or non-destructive nature of the test
- The need to divide a lot into sub-lots (so that stratified sampling can be applied to designated components of the lot)
- The cost of the sampling plan
- Risk assessment (see Section 2.2.5): Inspection systems, incorporating appropriate sampling plans, and designed to ensure food safety should be operated on the basis of objective risk assessment appropriate to the circumstances. Whenever possible, the risk assessment methodology employed should be consistent with internationally accepted approaches; and should be based on current available scientific evidence.

The precise definition of an acceptance sampling procedure will require the setting or selection of:

- The characteristic to be measured
- Lot size
- An attribute or variables plan
- The Limiting Quality (LQ) level, for isolated lots; or the AQL (Acceptable Quality Level), for a continuous series of lots
- The level of inspection
- The size of the sample
- The criteria for acceptance or rejection of the lot
- The procedures to be adopted in cases of dispute

2.2 COMMONLY USED TERMS AND NOTIONS

The definitions of sampling terms used in these guidelines are mostly those specified in ISO 7002.

Some of the more commonly used terms in acceptance sampling are described in this section.

2.2.1 Lot

A lot is a definite quantity of some commodity manufactured or produced under conditions which are presumed uniform.

Note : A consignment is a portion of a lot. But in the case of statistical inspection, the consignment shall be considered as a new lot for the interpretation of the results.

2.2.2 Sample

Set composed of one or several items (or a portion of matter) selected by different means in a population (or in an important quantity of matter). It is intended to provide an information which is characteristic of the

studied population (or matter), and possibly to form a basis for a decision concerning this population or this matter or the process which has produced it.

A **representative sample** is a sample in whose the characteristics of the lot from whose it is drawn are maintained. It is in particular the case when each of the items or increments of the lot has been given the same probability of entering the sample.

Note : Sections A.11 to A.17 of Annex A of the Standard ISO 7002 define the composite sample, the reference sample, the global sample, the test sample, the laboratory sample, the primary sample and the reduced sample.

2.2.3 Sampling

Procedure used for drawing or forming a sample.

2.2.4 Sampling error

Part of the total estimation error due to one or several of the following parameters :
- the heterogeneity of the inspected characteristics,
- the random nature of a sampling,
- the known and acceptable characteristics of the sampling plans.

2.2.5 Item or increment

a) Item : Item drawn in view of forming a sample.
b) Increment : Quantity of matter drawn at one time in a larger quantity of matter in view of forming a sample.

2.2.6 Sampling plan

Planned procedure which enables to choose, draw, separate samples from a lot, in order to get the information needed, such as a decision on the lot can be taken.

2.2.7 The Characteristic

A characteristic *is a property which helps to identify, or differentiate between, items within a given lot*. The characteristic may be either quantitative (by variables) or qualitative (by attributes). Three types of characteristic, and associated types of sampling plan may be illustrated as follows:

Type of Characteristic	Type of Sampling Plan
Commodity defects (e.g. as applied to visual defects such as loss of colour, mis-grading, extraneous matter etc)	'Attributes' (e.g. as in Codex Sampling Plans for Prepackaged Foods, CAC/RM 42-1969[6])
Compositional characteristics: these may be normally distributed (e.g. most analytically determined compositional characteristics such as moisture content) or they may be non-normally distributed.	'Variables with unknown standard deviation' for normally distributed characteristics and 'attributes' for characteristics whose distributions deviate significantly from normal
Health-related properties (e.g. in the assessment of microbiological spoilage, microbial hazards, irregularly occurring chemical contaminants etc)	Specified sampling plans to be proposed appropriate to each individual situation (e.g. the IDF 113A:1990 and ICMSF (Section 3.3) Standards. Plans to determine incidence rates in a population may be used.

2.2.8 Homogeneity

A lot is **homogenous** *relative to a given characteristic* if the characteristic is uniformly distributed

[6] The Codex Alimentarius Commission at its 22nd Session (June 1997) abolished the CAC/RM Numbering System.

throughout the lot[7]. A lot is **heterogeneous** relative to a given characteristic if the characteristic is **not** uniformly distributed throughout the lot. Items in a lot may be homogenous on one characteristic whilst heterogeneous on another characteristic.

2.2.9 Defects (Nonconformities) and Critical Nonconformities

A *defect (nonconformity)* occurs within an item when one, or more, *quality characteristic* does not meet its established quality specification. A *defective item* contains one or more defects.

Lot quality may be judged in terms of the acceptable *percentage of defective items* or the *maximum number of defects (nonconformities) per hundred items, in respect of any type of defects* (see also Section 2.2.7).

Most acceptance sampling involves the evaluation of *more than one quality characteristic,* which may differ in importance with respect to quality and/or economic considerations. Consequently, it is recommended that nonconformities are classified as follows, according to their degree of seriousness (see also Section 2.2.7):

- **Class A:** Those nonconformities considered to be of the highest concern in terms of the quality and/or safety of the product
- **Class B:** Those nonconformities considered to be less important than the Class A nonconformities

2.2.10 The Acceptable Quality Level (AQL) and Limiting Quality (LQ) Level

The inspection of a lot using either an attributes or variables sampling plan will allow the quality of the lot to be determined.

The **Acceptable Quality Level** (AQL) is an indexing criterion applied to *a continuous series of lots* which corresponds to a maximum rate of acceptable defective items in lots (or the maximum number of defective items per hundred items). This is a quality goal fixed by the profession. This does not mean that all the lots having a rate of defective items greater than AQL will be rejected at the control ,but that the more the rate of defective items is far from the AQL, the more the probability of rejecting a lot at control is high. For a given size of sample, the more the AQL of the plan is low, the more the protection of the consumer against the lots having defective items is high, and the more the requirement for the producer to conform with sufficiently high quality requirements is high. Any value for AQL shall be realistic in practice and economically viable.

Meanwhile, it should be recognized that the selection of a value for the AQL depends on the specific characteristic considered and of its relevance (economic or other) for the standard in its whole. A risk analysis shall be undertaken in order to assess and the possibility and the severity of negative impacts on public health caused, for example, by the presence in food products of additives, contaminants, residues, toxins or pathogenic micro-organisms.

The characteristics which may be linked to critical defects (for example to sanitary risk) shall be associated with a low AQL (i.e. 0,1 % to 0,65 %) whereas the compositional characteristics such as the fat or water content, etc may be associated with higher AQL (for example 2,5 % or 6,5 % are values often used for milk products). The AQL is used as an indexing device in the tables of the Standards ISO 2859-1, ISO 3951 and in some tables of ISO 8422 and ISO 8423 (see section 1).

The **Limiting Quality** (LQ) is applied when *a lot is considered in isolation*. It is a quality level (expressed, for example, as percentage nonconforming items in the lot) which corresponds to a specified and relatively low probability of acceptance of a lot having a rate of defective items of LQ. Generally, the LQ corresponds to the rate of defective items of lots accepted at control in 10 % of the cases. LQ is an indexing device used in ISO 2859-2 (where it is recommended that the LQ is set at least three times the desired AQL, in order to ensure that lots of acceptable quality have a reasonable probability of acceptance).

The users of sampling plans shall mandatorily agree on the choice on the AQL or LQ of the plan used for the quality control of the lots.

For a given product, a single AQL (or LQ) should be allocated to each of the two classes of nonconformities specified in Section 2.2.9, a low AQL (for ex 0,65 %) being allocated to Class A nonconformities (ex :

[7] After checking by a statistical test for comparison of 2 samples, i.e. parametric or non parametric tests of the characteristic.

pesticide content in follow-up milk), and a higher AQL (for ex 6,5%) being allocated to Class B nonconformities (ex : protein content in follow-up milk).

Consequently, there will be a separate sampling plan for each of the two AQLs (LQs), and **a lot will only be accepted if it is accepted by each of the plans**. The same sample may be used for each class provided the evaluation is not destructive for more than one type of nonconformity. If two samples must be collected they should be taken simultaneously for minimising the variations.

2.2.11 Responsible Authority

The **responsible authority** will be the official designated by the importing country; and will normally be responsible, for example, for setting the '*inspection level'* and for the introduction of *'switching rules'* (see 2.2.12).

2.2.12 Inspection Levels and Switching Rules

The **inspection level** *relates the sample size to the lot size and hence to the discrimination afforded between 'good' and 'poor' quality*. For example, Tables I and I-A of ISO 2859-1:1989 (E) and ISO 3951:1989 (E) respectively provide seven and five inspection levels. For a given AQL the lower the inspection level number the greater is the risk of accepting poor quality lots.

The inspection level should be set by the '*responsible authority*'. *Unless otherwise specified, inspection level II shall be used*. Levels I and III should be used when less or more discrimination, respectively, is required. Level II affords less than double the sample size of Level I, Level III gives about one and a half times the sample size of Level II. The 'special' levels (S-1 to S-4) should be used where relatively small sample sizes are required and large sampling risks can and/or must be tolerated.

A sampling scheme involves '**switching**' between normal, tightened and reduced inspection sampling plans. It is recommended that all Commodity Committees include switching rules in those sampling plans applied to a continuing series of lots.

Normal inspection is designed to protect the producer against having a high proportion of lots rejected when the quality of the product is better than the AQL. However, if two out of any five (or fewer) successive lots are not accepted, then tightened inspection must be introduced. On the other hand, if production quality is consistently better than the AQL, sampling costs may be reduced (at the discretion of the responsible authority) by the introduction of reduced-inspection sampling plans.

Switching rules for a continuous series of lots are described in detail in Sections 4.2.2 and 4.3.4.

2.2.13 Acceptance Number

For a given attributes sampling plan, the **acceptance number** *is the maximum number of nonconforming units, or the maximum number of nonconformities, allowed in the sample if the lot is to be accepted. Zero acceptance number plans* are described in Sections 2.3, 2.4.3 and 3.1.

2.2.14 Lot Size and Sample Size

For internationally traded commodities, the lot size is usually specified in the shipping manifest. If a different lot size is to be used for sampling purposes, this should be clearly stipulated in the standard by the appropriate Commodity Committee.

There is no simple mathematical relationship between sample size and lot size. In most instances, the lot size is not important provided the sample size is small in comparison. It is the absolute sample size that is more important rather than its relationship to the size of the lot. However, 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, especially when the lot is not homogenous.

With a large lot it is possible and economic to take a large sample whilst maintaining a large lot-to-sample ratio and, thereby, achieving better discrimination (between acceptable and unacceptable lots). Furthermore, for a given sampling efficiency, the sample size will not increase as rapidly as the lot size and will not increase at all after a certain lot size. However, there are a number of reasons for limiting the lot size:

- the formation of larger lots may result in the inclusion of a widely varying quality
- the production or supply rate may be too low to permit the formation of large lots
- storage and handling practicalities may preclude large lots
- accessibility for drawing random samples may be difficult with large lots
- the economic consequence of non-acceptance of a large lot may be large.

2.2.15 Operating Characteristic Curve

For a given sampling plan, an **Operating Characteristic (OC) curve** describes the probability of acceptance of a lot as a function of its actual quality. It relates the rate of defective items in lots with the probability of accepting these lots at control. Section 4.1.1 develops the principle of such a curve and illustrates it with an example.

2.3 SAMPLING PROCEDURES

2.3.1 Employment of Authorized Sampling Officers

It is highly recommended that the sampling is *performed by persons trained and authorized in the techniques of sample collection* by the importing country.

2.3.2 Material to be Sampled

Each lot which is to be examined must be clearly defined. The appropriate Codex Commodity Committee should stipulate how a consignment should be handled in instances where no lot designation exists.

2.3.3 Representative sampling

Procedure used for drawing or forming a representative sample[8].

In order to avoid any dispute on the representativeness of the sample, the random sampling shall be mandatory chosen, whenever possible.

Random sampling involves the collection of *n* items from a lot of *N* items in such a way that all possible combinations of *n* items have the same probability of being collected.

Assuming the items can be numbered or ordered, even virtually when it is not possible to have individual items (for ex. in the case of a tank of milk or of a silo of grains), the choice of the items or of the increments entering into the sample shall be done as follows :

1. To number all the items or increments of the lot (true or virtual)
2. The numbers of the items or increments to be sampled are determined randomly using Table 3 of the Standard ISO 2859-0:1995 or any approved table of random numbers.

The collection of samples is most likely to be performed in a random manner when items (or increments) are removed during the loading or unloading of lots.

If the commodity is heterogeneous, the random sampling may not be representative of the lot. In this case, the stratified sampling may be a solution. The stratified sampling consists in differentiating parts of the lot (called layers or zones) as homogenous as possible, then to sample randomly in each of these layers following specified instructions which may be drafted by the Codex product committees. Each layer can then be inspected by punctual sampling which usually includes from 2 to 20 items or increments per sample. (see the sampling plans of ISO 2859-1 of letter-codes A to F at the inspection level II). But before sampling, it is necessary, where appropriate, to refer to the specific instructions of the Codex product committees.

When it is not possible to refer to a random situation[9], for example in a very large store where the goods are badly tidied and when the production process includes a periodic phenomenon (for ex a contaminant which

[8] See the definition of a representative sample in 2.2.2.

[9] The assessment of such a situation can be done, for a periodic phenomenon, by looking at the process control chart, for the storage conditions, or by obtaining informations from storage managers, laboratories, professional organisations.

is specifically located in a particular area of the silo or a regulator detuned every each k seconds, such as every k seconds the products packaged by this regulator have defaults), it is mandatory :

1. To avoid to choose systematically the items more easily accessible or which can be differentiated by a visible characteristic.
2. In the case of periodic phenomena, to avoid to sample every k seconds or every k^{th} package, or every k^{th} centimetres, to take an unit every n palette, pre-package,…

2.3.4 Preparation of samples

2.3.4.1 Primary Samples

A **primary sample** *is the 'portion of product' collected from a lot during the first stage of the sampling process*, and will normally be in the form of an *item* (if collected from a lot of prepacked products) or of an *increment* (if collected from a bulk lot). (However, an 'increment' may be considered to be an 'item' if measurements are made on individual increments.) As far as is practicable, primary samples should be taken throughout the lot and **departures from this requirement must be recorded**. Sufficient primary samples of similar size should be collected to facilitate laboratory analysis. In the course of taking the primary samples (items or increments), and in all subsequent procedures, *precautions must be taken to avoid contamination of the samples or any other changes which would adversely affect the amount of residues or the analytical determinations, or make the laboratory sample not representative of the composite sample.*

2.3.4.2 Composite Sample

When required by the sampling plan, a **composite sample** is produced by combining the primary samples (items) from a lot of *prepacked* products; or by combining the primary samples (increments) from a *bulk* (*not* prepackaged) lot.

2.3.4.3 Final Sample

The *bulk or bulked sample* should, if possible, constitute the **final sample** and be submitted to the laboratory for analysis. If the bulk/bulked sample is too large, the final sample may be prepared from it by a suitable *method of reduction*. In this process, however, individual items must not be cut or divided.

National legislative needs may require that the final sample be subdivided into two or more portions for separate analysis. Each portion must be representative of the final sample.

2.3.5 Packaging and Transmission of Laboratory Samples

The sample finally submitted to the laboratory is described as the **laboratory sample** and will take the form of either the final sample or a representative portion of the final sample.

The laboratory sample must be placed in a clean inert container offering adequate protection from external contamination and protection against damage to the sample in transit. The container must then be sealed in such a manner that unauthorized opening is detectable, and sent to the laboratory as soon as possible taking any necessary precautions against leakage or spoilage, e.g., frozen foods should be kept frozen and perishable samples should be kept cooled or frozen, as appropriate.

2.3.6 Sampling reports

Every sampling act implies the drafting of a sampling report as described in clause 4.16 of the Standard ISO 7002 and indicating in particular the reason for sampling, the origin of the sample, the sampling method and the date and place of sampling, together with any additional information likely to be of assistance to the analyst, such as transport time and conditions. The samples, in particular the ones for the laboratory, shall be clearly identified.

In case of any departure from the recommended sampling procedure (when it was necessary, for any reason, to deviate from the recommended procedure), it is necessary to append to the sampling report another detailed report on the deviating procedure which has been actually followed.

2.3.7 Estimation error

Quantitative results are of only limited value if they are not accompanied by some estimate of the *random* (unpredictable) and *systematic (*predictable*)* errors in them. (*Random* errors affect the precision of the result, whereas *systematic* errors affect accuracy.).

Sampling plans are associated with two types of error: *sampling error* (caused by the sample failing to accurately represent the population from which it was collected); and *measurement error* (caused by the measured value of the characteristic failing to accurately represent the true value of the characteristic within the sample). It is highly desirable that the sampling and measurement errors associated with any sampling plan should be quantified and minimised.

2.4 Types of sampling single plans

2.4.1 Single sampling plans for inspections of percent nonconform items

2.4.1.1 Principles of inspection by attributes of percent nonconforming

The following text and curves present simply the principles of inspection by single sampling plans by attributes and by variables of percent nonconforming as well as their efficacy.

A sampling plan by attributes is a method for evaluating the quality of a lot which consists in qualifying each increment of the sample as a conforming or nonconforming characteristic or attribute, depending on whether the Codex standard specification is complied with or not. This characteristic is either qualitative (for example the presence of a blemish on fruit) or quantitative (for example an over-the-limit sodium content of a dietary food). The number of increments having the nonconforming attribute are then counted and if the acceptance number set by the plan is not exceeded the lot is accepted, otherwise it is refused.

> EXAMPLE 1 : A single sampling plan by attributes of AQL = 2,5 % to inspect the sodium content of a lot of dietary cheese low in sodium for which the maximum sodium content is set by Codex standard 53-1981 at 120 milligrams per 100 grams of commodity.
>
> Decision to be taken according to this plan:
>
> The lot is accepted if there is no nonconforming increment in a sample of five increments, a nonconforming increment being one whose sodium content -given the analytical tolerances- is higher than the specification relative to sodium in dietary cheeses, i.e. 120 milligrams.
>
> The following Figure 1 is the characteristic operating curve of this plan. It shows that in 50 % of the cases, lots having 13 % of defective items are accepted at inspection.

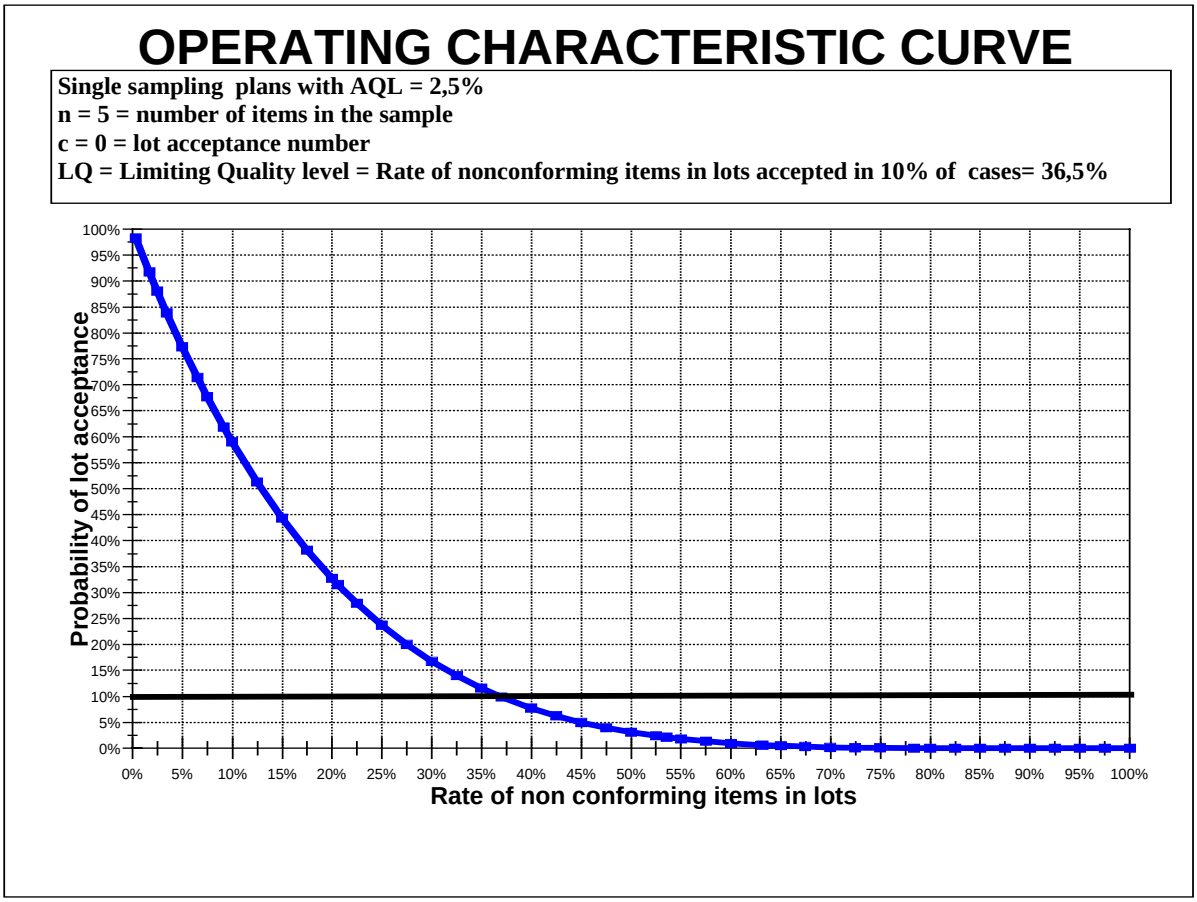


FIGURE 1

EXAMPLE 2 : Single sampling plan by attributes, AQL = 6,5 %, for the inspection of the quality of pre-packed quick frozen peas.

Characteristics of the plan :
Criterion of non-conformity : the pre-packed bag contains more than 15 % m/m of defective peas (blond peas, blemished peas,…)
Number of sample units : n=13
AQL = 6,5 %
Acceptance number : Ac = 2 = maximum acceptable number of defective bags in the sample (acceptance criterion of the lot)
Rejection number : Re = 3 = minimum number of defective bags in the sample which implies the rejection of the lot (rejection criterion of the lot)

Decision to be taken according to this plan:
The lot is accepted if there is no more than 2 defective bags in a sample of 13 bags.

2.4.1.2 Principles of inspection by variables of percent nonconforming

2.4.1.2.1 General

A sampling plan by variables is a method for evaluating the quality of a lot which consists in measuring for each item the value of a variable characterizing the inspected commodity

- EXAMPLES[10];

[10] In order to well illustrate the difference between the plans by attributes and by variables, the example of dietary cheese at maximum content of sodium is also taken for the plans by variables.

- The maximum sodium content U of a dietary cheese low in sodium, for whose the maximum sodium content is fixed by the Codex standard 53-1981 at 120 milligrams per 100 grams of product ;
- The minimum fat content L of a whole milk;
- A range of values, such as the vitamin A content of an infant formula, between L and U.

The inspection consists in measuring the variable characterising the inspected good for each of the *n* items forming the sample, then in calculating the mean value *x* of these *n* items of the sample

The decision concerning the lot is taken by comparing this mean content *x* with the numeric value of an algebraic expression including :

- either U the maximum value of the specification (case of a maximum value to inspect), either L the minimum value of the specification (case of a minimum value to inspect), either L and U (case of a range of values to inspect) ;
- the standard deviation of the values of the variable inspected in the lot ;
- an acceptance constant K.

The algebraic expression depends also on the fact that the standard deviation is known or unknown. The decision formulae are given in 2.4.1.2.2 and 2.4.1.2.3.

2.4.1.2.2 The standard deviation σ of the distribution is known (σ method)

This is the case for example of inspections made by professionals who, owing to the large number of inspections they make, know the standard deviation sufficiently precisely to consider it as known. The following table 3 defines the acceptance/rejection rules of the lots.

	Inspection of a minimum value L $x \geq L$	Inspection of a maximum value U $x \leq U$	Inspection of a range of values $L \leq x \leq U$
Lot is accepted	$\bar{x} \geq L + K\sigma$	$\bar{x} \leq U - K\sigma$	$L + K\sigma \leq \bar{x} \leq U - K\sigma$
Lot is refused	$\bar{x} < L + K\sigma$	$\bar{x} > U - K\sigma$	$U-L < 2K\sigma$

TABLE 3

EXAMPLE : inspection of the maximum sodium content U of a lot of dietary cheese low in sodium for which the maximum sodium content is set by the Codex standard 53-1981 at 120 milligrams per 100 grams of commodity

Inspected value U = 120 milligrams of sodium per 100 grams of dietary cheese

Data of the chosen sampling plan, from the Standard ISO 3951 :

- n = 5, number of items in the sample;
- K = 1,39, acceptance constant;
- AQL = 2,5 %.

Results of measurements :

- x_1 denotes the sodium content measured in the first item, = 118 mg ;
- x_2 denotes the sodium content measured in the second item, = 123 mg ;
- x_3 denotes the sodium content measured in the third item, = 117 mg ;
- x_4 denotes the sodium content measured in the fourth item, = 121 mg ;
- x_5 denotes the sodium content measured in the fifth item, = 125 mg ;
- $\bar{x}$ denotes the mean of the sodium contents obtained on the sample of five items

$$\bar{x} = \frac{x_1 + x_2 + x_3 + x_4 + x_5}{5} = 120{,}8 \text{ mg}$$

- σ denotes the standard deviation calculated on the sample :

$$\sigma = \sqrt{\sum_{i=1}^{i=n} \frac{\left(x_i - \bar{x}\right)^2}{n}} = 2{,}99 \text{ mg}$$

- Conclusion : knowing that U - Kσ = 120 – (1,39 x 2,99) = 115,8 mg, then $\bar{x} >$ U - Kσ and the lot is rejected.
- The operating characteristic curve of the plan by variables is given in the figure 2.

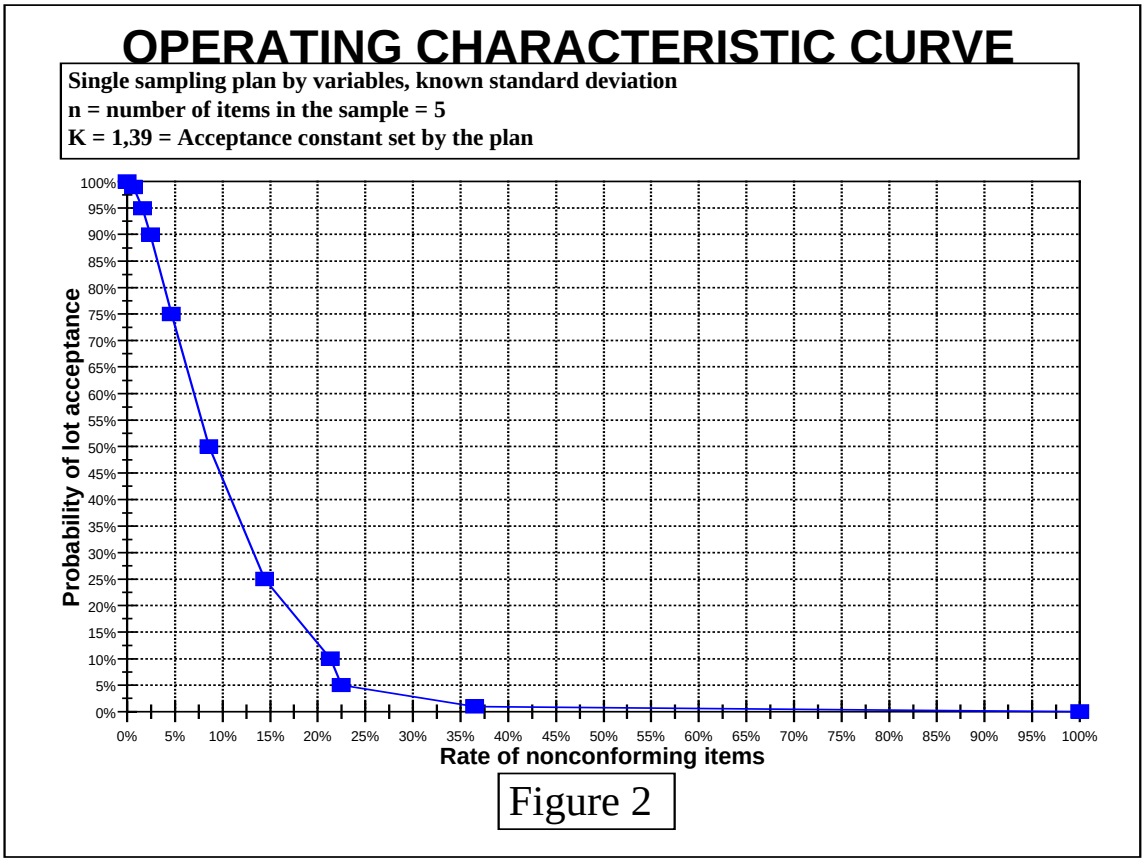


Figure 2

FIGURE 2

2.4.1.2.3 The standard deviation σ of the distribution is unknown (method s)

When the standard-deviation σ of the distribution of values is unknown (for example in the case of inspections made by official inspection departments which, owing to the insufficient number of inspections they make, do not know the standard-deviation sufficiently precisely to consider it as known), the method is called the s method, since the standard-deviation σ is estimated by $s = \sqrt{\sum_{i=1}^{i=n} \frac{\left(x_i - \bar{x}\right)^2}{n-1}}$, called the standard deviation estimator.

In this case, the distribution of means calculated on the sample follows a Student distribution with n degrees of freedom. The following table 4 defines the acceptance/rejection rules of the lots.

	Inspection of a minimum value L $x \geq L$	Inspection of a maximum value U $x \leq U$	Inspection of a range of values $L \leq x \leq U$
Lot is accepted	$\bar{x} \geq L + Ks$	$\bar{x} \leq U - Ks$	$L + Ks \leq \bar{x} \leq U - Ks$
Lot is refused	$\bar{x} < L + Ks$	$\bar{x} > U - Ks$	$U-L < 2K\sigma$

TABLE 4

EXAMPLE : inspection of the maximum sodium content U of a lot of dietary cheese low in sodium for which the maximum sodium content is set by the Codex standard 53-1981 at 120 milligrams per 100 grams of commodity

Inspected value U = 120 milligrams of sodium per 100 grams of dietary cheese

Data of the chosen sampling plan, from the Standard ISO 3951 :
- n = 5, number of items in the sample;
- K = 1,24, acceptance constant;
- AQL = 2,5 %.

Results of measurements[11] :
- x_1 denotes the sodium content measured in the first item, = 118 mg ;
- x_2 denotes the sodium content measured in the second item, = 123 mg ;
- x_3 denotes the sodium content measured in the third item, = 117 mg ;
- x_4 denotes the sodium content measured in the fourth item, = 121 mg ;
- x_5 denotes the sodium content measured in the fifth item, = 125 mg ;
- $\bar{x}$ denotes the mean of the sodium contents obtained on the sample of five items $\bar{x} = \frac{x_1 + x_2 + x_3 + x_4 + x_5}{5}$ = 120,8 mg
- s denotes the standard deviation estimator calculated on the sample :

$$s = \sqrt{\sum_{i=1}^{i=n} \frac{\left(x_i - \bar{x}\right)^2}{n-1}} = 3{,}35 \text{ mg}$$

- Conclusion : knowing that U - Ks = 120 – (1,24 x 3,35) = 115,8 mg, then $\bar{x} >$ U - Ks and the lot is rejected (see Table 3)

2.4.1.2.4 Comparison of σ and s methods

The difference between the two methods comes from the value of LQ (defective rate in the lots accepted in 10 % of cases), see examples of 2.4.1.2.2 and 2.4.1.2.3. In these examples :

[11] In order to highlight the difference with the σ method, the numerical values are identical to whose indicated in the case of the σ method.

σ method : the QL is 20,7 %, consequence of the characteristics of the plan (AQL = 2,5 %, n = 5, K = 1,39).

s method : the QL is 35 %, consequence of the characteristics of the plan (AQL = 2,5 %, n = 5, K = 1,24).

The following Table 5 and Figure 3 compare the efficiency of these 2 plans and show that the σ method is more efficient that the s method, since the more the lots contain defective items, the less these lots will be accepted at inspection by the s method.

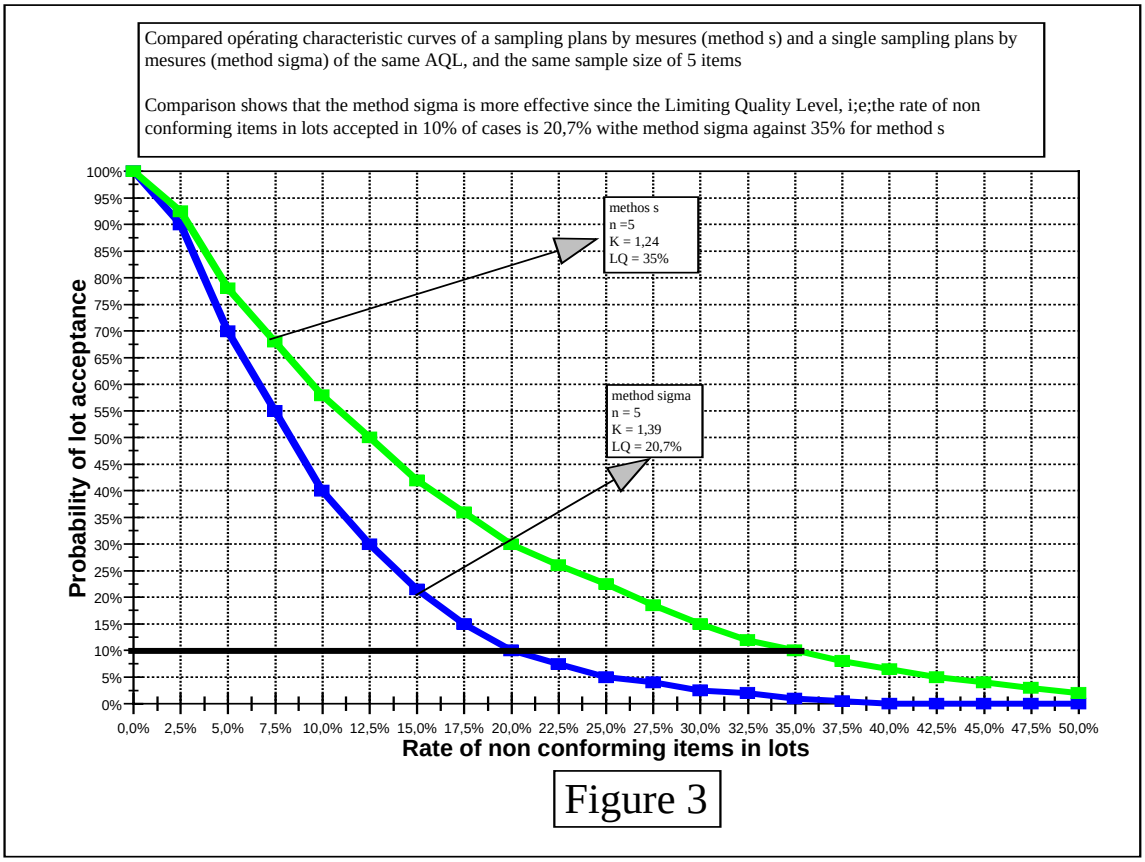


Figure 3

Figure 3

Defective rates in the lots	***Probability to accept these lots*** ***σ method***	***Probability to accept these lots*** ***s method***
0%	*100%*	*100%*
0,4%	*99,8%*	*99%*
1,38%	*96,5%*	*95%*
2,48%	*90%*	*90%*
5,78%	*65,9%*	*75%*
12,47%	*29,7%*	*50%*
22,88%	*7,4%*	*25%*
34,98%	*1,2%*	*10%*
42,97%	*0,3%*	*5%*
58,11%	*0%*	*1%*
0%	*0%*	*0%*

TABLE 5

2.4.1.3 Compared effectiveness of an inspection of defective rate by attributes and of an inspection of defective rate by variables

The following Figure 4 which compares the efficacy of a variables plan and an attributes plan, of the same AQL 2,5% and having a sample size of five items, shows that the variables plan is more effective than the attributes plan since the limiting quality of lots accepted in 10% of cases is lower with variables plans (20,7 %) than with attributes plans (36%).

Effectiveness compared of an inspection of defective rate between a variables plan and an attributes plan of same AQL =2,5%, and same simple size (n= 5 items in the sample) The comparison shows that the variables plan is more effective since the Limiting Quality Level , i.e. the rate of non conforming items in lots accepted in 10% of cases is 21,4% with variables plan as against 30% for attributes plan

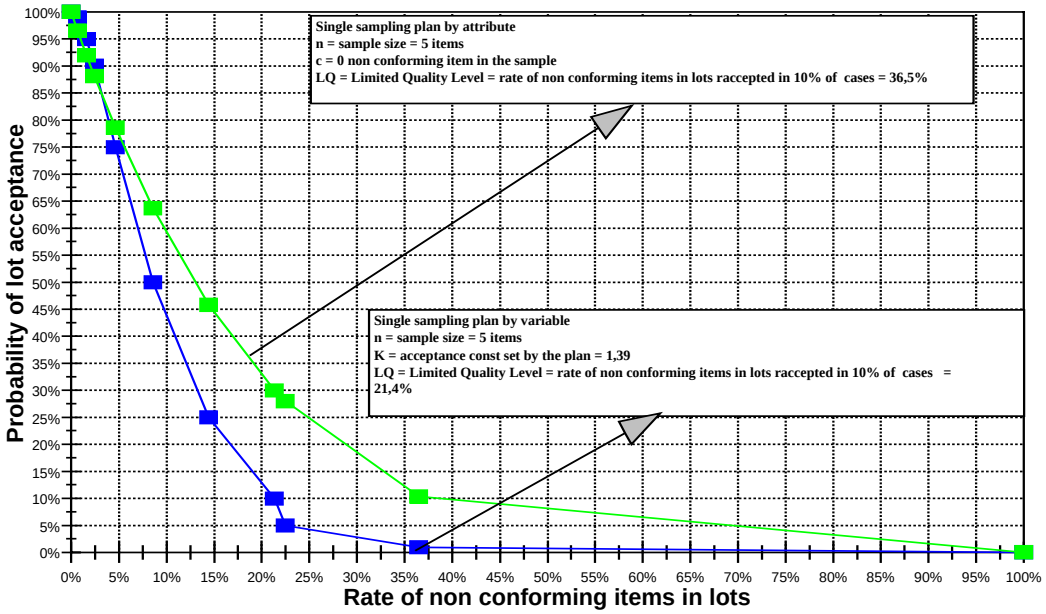
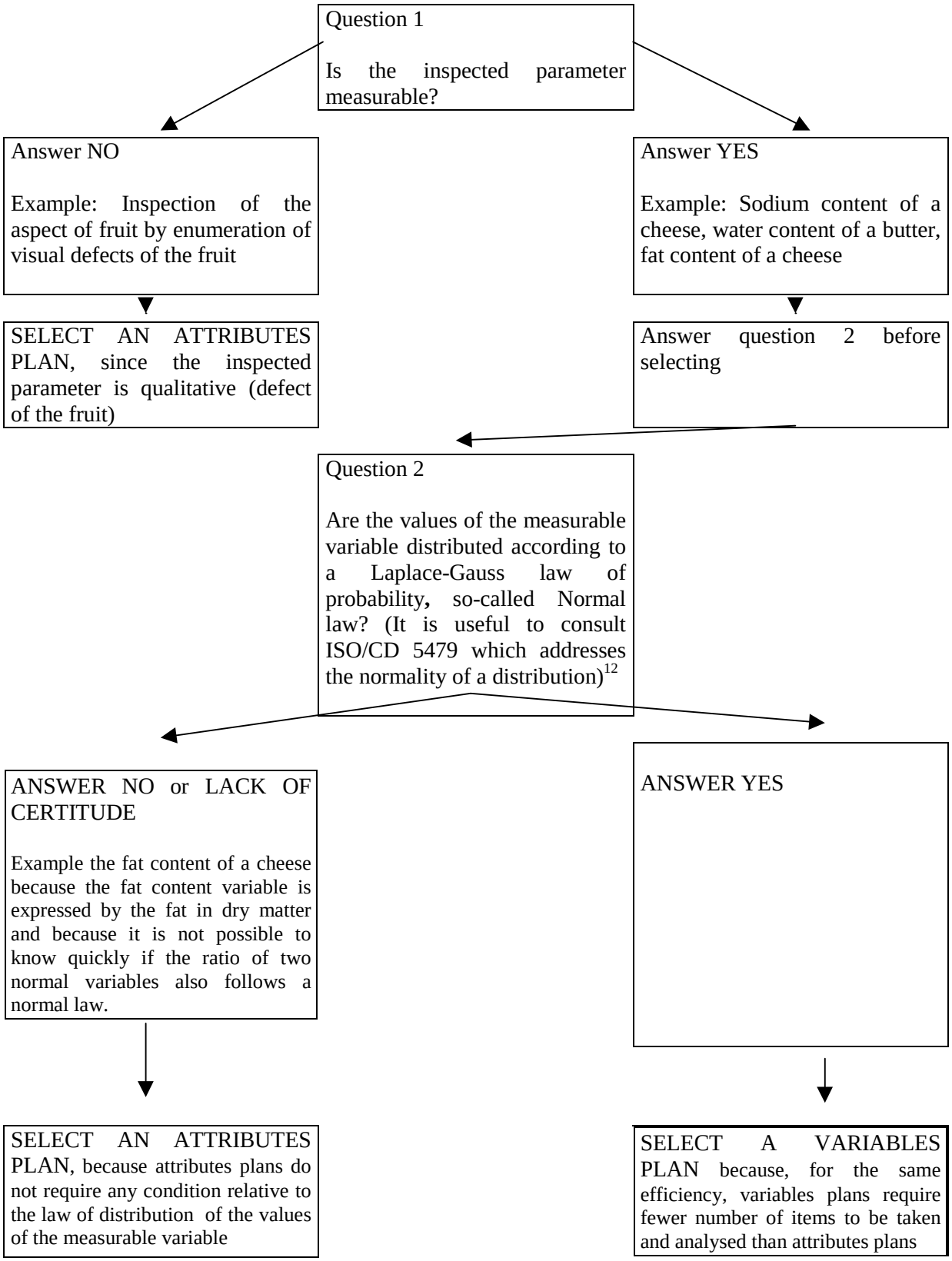


Figure 4

FIGURE 4

2.4.1.4 The selection of an attributes plan or a variables plan must be made after having gone through the following decision tree:



[12] A variable transformation making the distribution of the transformed variable normal cannot be used unless there are international scientific references justifying it.

2.4.1.5 Comparative advantages and disadvantages of attributes plans and variables plans

When it is possible to implement either an attributes plan or a variables plan, for example for the inspection of the sodium content of a dietary cheese, the selection must be made after having consulted in particular the following Table 6 on the comparative advantages and disadvantages of the plans[13].

	ADVANTAGES	DISADVANTAGES
ATTRIBUTES PLANS	No condition on the mathematical law of distribution of the variable inspected Greater simplicity of processing the results on the sample	Less effective than variables plans for a same sample size of n increments (the LQ is higher); more costly than variables plans because the collected sample requires more increments than those required, for the same efficacy, by a variables plan
VARIABLES PLANS	More effective than attributes plans for a same sample size of n increments (the LQ is lower); for a same AQL they are less expensive than attributes plans because the sample collected requires fewer increments than those required, for a same efficacy, by attributes plans	They cannot be used in all cases because to validate the calculation formulas the mathematical law of distribution of the inspected variable must necessarily follow a normal law

Table 6

The sample sizes required when inspecting by attributes and variables are compared in the following table 7:

Comparison of sample sizes in inspection by attributes and by variables		
Sample size code letter[a]	**Sample sizes**	
	Inspection by attributes	Inspection by variables
C	5	4
F	20	10
H	50	20
K	125	50
N	500	150
a) From Table 1 in ISO TR 8550, the code letter gives the combinations of lot size and of "inspection levels" (section 2.2.12)		

Table 7 (after Table 1 in ISO/TR 8550*)*

2.4.1.6 Recommended situation for attribute sampling plans

Attributes plans are more robust than variables methods (not subject to assumptions of distribution shape) and are simpler to operate. **Sampling by attributes is recommended when evaluating isolated lots.** If necessary, *measurements (variables) should be converted to attributes*, in order to facilitate attribute sampling.

2.4.1.7 Recommended situation for variable plans

The variables method requires a smaller sample size than the attributes method to attain a given degree of protection against incorrect decisions - an important consideration when the sampling is destructive.

[13] When the inspection of two specifications, for example the fat content and the sodium content of a dietary cheese, necessitates the implementation of a plan by attributes (for the fat content) and by variables (for the sodium content), it is recommended, for the practicality of inspection, to choose a plan by attributes for the two specifications.

However, *since each quality characteristic has to be considered separately, the variables method becomes less suitable as the number of measurements to be made on a single item increases.*

2.4.2 Zero Acceptance Number Sampling Plans

(see the Standard ANSI/EIA-585)

This standard addresses the need for sampling plans, *based upon a **zero** acceptance number*, which address quality (non-conformance) levels in the parts per million (ppm) range within *isolated lots*. The standard does not address minor nonconformities.

Zero acceptance sampling plans in EIA-585 are applicable, but not limited, to inspection of (a) end items and (b) components and raw material. The selection of the appropriate plan depends upon the amount of consumer protection desired for a selected PPM level of desired product quality, and the size of the lot.

For the sample inspection of isolated lots, the plans in Appendix A of Standard EIA-585 may be used, or exact Operating Characteristic Curves can be generated by using the equation at the bottom of Table 1 in the standard. Appendix B includes typical sampling plans for different values of protection for five different lot proportion nonconforming levels.

2.4.3 Sampling plans for inspection of critical nonconformities

C*ritical nonconformities* render the items hazardous, or potentially hazardous, and can result in illness or death.

2.4.3.1 Procedure of the Standard ISO 2859-0

The following procedure may be used to establish the appropriate sample size (see **ISO 2859-0; Sampling procedures for inspection by attributes - Part 0**):

- a simple formula is used which relates :
  - (a) the maximum number d of critical nonconformities/nonconforming items admitted in the lot ;
  - (b) N the lot size;
  - (c) n the sample size;
  - (d) the risk β one is prepared to take of failing to find a nonconformity/nonconforming item, i.e. the probability of non detecting at least one critical nonconformity[14];
  - (e) the probability p of maximum nonconforming items admitted in the inspected lot[15] p = d/N, d = Np rounded down to the nearest integer;
  - the sample size n is obtained from the following equation (by rounding-up to the nearest integer):

$$n = (N - d/2)\,(1 - \beta^{1/(d+1)})$$

  - the lot is accepted if no critical nonconformities are found in the sample.

EXAMPLE : Detection of the contamination of apples by lead

Determination of sample size for the inspection of the lead content per apple, in a lot of N = 3454 apples where :

[14] It is essential to choose β inferior or equal to 0,1 %.

[15] P shall be inferior or equal to 0,2%.

- p, the maximum percentage of nonconforming critical items, is 0,2%
- the maximum risk β of accepting of non detecting a nonconforming item is 0,1%
- Ac, the acceptance criterion of the lot, is 0 (no nonconforming item in the sample)
- Re, the rejection criterion of the lot; is 1 (at least 1 nonconforming item in the sample).

Calculation of d : d = Np = 3454*0,002 = 6,908, rounded down to the nearest integer = 6

Calculation of n : $n = (N - d/2)\ (1 - \beta^{1/(d+1)}) = 2165$

2.4.3.2 Procedure of Schilling (1978)[16]

A **Lot Sensitive Sampling Plan (LSP)** is based upon the hypergeometric probability distribution. It is easy to use and is based upon the concept of acceptance with *zero defectives in the sample*. A LSP is especially recommended for the evaluation of *isolated lots,* and may be summarised as follows:

- Specify lot size
- Specify the limiting quality level (p_t) that is to be protected against by the plan
- Compute the product $D = Np_t$
- Enter the table (see overleaf) at the nearest value of D and read the corresponding value of 'f' (fraction of lot inspected) as the sum of the associated row and column headings
- The sampling plan is:
  sample size, n = fN (always rounded up);
  acceptance number, c = 0.
- The sampling plan is applied by:
  randomly collecting a sample of n items from a lot of N items;
  rejecting the lot if any defective items are found in the sample.

A Lot Sensitive Sampling Plan

Values of $D=Np_t$ Corresponding to f

f	.00	.01	.02	.03	.04	.05	.06	.07	.08	.09
.9	1.0000	.9562	.9117	.8659	.8184	.7686	.7153	.6567	.5886	.5000
.8	1.4307	1.3865	1.3428	1.2995	1.2565	1.2137	1.1711	1.1286	1.0860	1.0432
.7	1.9125	1.8601	1.8088	1.7586	1.7093	1.6610	1.6135	1.5667	1.5207	1.4754
.6	2.5129	2.4454	2.3797	2.3159	2.2538	2.1933	2.1344	2.0769	2.0208	1.9660
.5	3.3219	3.2278	3.1372	3.0497	2.9652	2.8836	2.8047	2.7283	2.6543	2.5825
.4	4.5076	4.3640	4.2270	4.0963	3.9712	3.8515	3.7368	3.6268	3.5212	3.4196
.3	6.4557	6.2054	5.9705	5.7496	5.5415	5.3451	5.1594	4.9836	4.8168	4.6583
.2	10.3186	9.7682	9.2674	8.8099	8.3902	8.0039	7.6471	7.3165	7.0093	6.7231
.1	21.8543	19.7589	18.0124	16.5342	15.2668	14.1681	13.2064	12.3576	11.6028	10.9272
.0	*	229.1053	113.9741	75.5957	56.4055	44.8906	37.2133	31.7289	27.6150	24.4149

* For values of f<.01 use f=2.303/D; for infinite lot size use sample size $n=2.303/p_t$.
From Schilling (1978, p.48).

[16] The deletion of this section shall be discussed.

SECTION 3: THE SELECTION OF SAMPLING PLANS FOR SINGLE OR ISOLATED LOTS MOVING IN INTERNATIONAL TRADE

This section presents the rationale for **selecting sampling plans by attributes for single or isolated lots** moving in international trade. It lays down rules for:

- inspection by attributes indexed by the limiting quality (LQ) level (section 3.1)
- inspection by two or three class attributes for microbiological assessments (section 3.2)

3.1 SAMPLING PROCEDURES FOR INSPECTION BY ATTRIBUTES: SAMPLING PLANS INDEXED BY LIMITING QUALITY (LQ) FOR ISOLATED LOT INSPECTION

(see ISO 2859/2-1985 (E))

This ISO Standard provides sampling plans for application to single lots (procedure A, 3.1.1) or to lots isolated from a series (procedure B, 3.1.2) *where the 'switching rules' (see Section 2.2.10) are precluded*. Both procedures use the limiting quality (LQ; Section 2.2.5) as an indicator of the actual percentage nonconforming in the lots submitted. The associated Consumer's Risk (the probability of accepting a lot with the limiting quality level) is usually less than 10 per cent, but always below 13 per cent.

Procedure A is used when *both the producer and consumer wish to regard the lot in isolation*; and *it is also used as the default procedure* (i.e. it is used unless there is a specific instruction to use procedure B). Procedure A includes plans *with acceptance number zero*, and with sample sizes based upon the hypergeometric distribution of sampling results. **Procedure B** is used when *the producer regards the lot as one of a continuing series, but the consumer considers the lot in isolation*. This approach allows the producer to maintain consistent production procedures for a variety of consumers whilst any individual consumer is concerned with only one particular lot. Procedure B excludes plans with zero acceptance numbers, replacing them with one hundred percent evaluation.

Procedures A and B may be compared as follows:

Procedure A (default procedure)	Procedure B
Producer & consumer regard lot in isolation	Producer regards lot as one of continuing series Consumer regards lot in isolation
Identified by lot size and LQ	Identified by lot size, LQ & inspection level
Includes plans with an acceptance number of zero	Plans with an acceptance number of zero not included
Double & multiple plans can be used as alternatives to zero acceptance number plans	Double & multiple plans can be used as alternatives to single sampling plans

3.1.1 Procedure A: Producer and consumer regard lot in isolation

The application of procedure A may be illustrated as follows:
Summary of sampling plan
(Table D1 in ISO 2859/2-1985 (E))

Set LQ
↓
Select sample size (n) & acceptance number (Ac) (Table A in ISO 2859/2-1985 (E)) and collect sample
↓
Inspect each item in the sample
↓
Accept the lot if: number of nonconforming items ≤ Ac

3.1.2 Procedure B: Producer regards lot as one of a continuing series: Consumer regards lot in isolation

The application of procedure B may be summarised as follows:

Summary of sampling plans
Tables B1-B10, ISO 2859/2-1985(E)

Set LQ
↓
Select inspection level
(Table I in ISO 2859-1 : 1989 (E) and Table B6 in ISO 2859/2-1985(E))
↓
Select sample size, n & acceptance number, Ac (Tables B1-B10, ISO 2859/2-1985(E))
and collect sample
↓
Inspect each item in the sample
↓
Accept the lot if: number of nonconforming items ≤ Ac

3.2 TWO AND THREE CLASS ATTRIBUTES PLANS FOR MICROBIOLOGICAL ASSESSMENTS

(see : « Micro-organisms in Foods. 2. Sampling for microbiological analysis: Principles and specific applications »; International Commission on Microbiological Specifications for Foods, ICMSF, 1986, ISBN 0-632-01567-5).

3.2.1 Two-class Attributes Plans

Two-class attributes plans provide a simple means of inspection *where the sampling plan is defined by two values, n and c*. The value of n defines the sample size in terms of the number of items; and the value c denotes the maximum number of nonconforming items permitted in the sample. When undertaking a microbiological assessment, a maximum concentration of micro-organisms permitted in any item is denoted by m; any item contaminated at a concentration greater than m is considered to be nonconforming.

For a given value of c, the stringency (probability of rejection) of the plan will increase as n increases. Similarly, for a given value of n, the stringency will increase as c decreases. The equation of the OC of such plans is the following :

$$P_A = P\,[x \leq c] = \sum_{i=0}^{i=c} C_n^i p^i (1-p)^{n-i}$$

Where :
P_A = Probability to accept the lot
p = Defective rate in the lot, ie lots for which the concentration of micro-organisms is greater than m
i and x are whole discrete variables, varying between 0 and c

$$C_n^i = \frac{n!}{i!(n-i)!}$$

Summary of a two-class attributes plan

Set the value of M, n and c
↓
Collect the sample with n items
↓
Inspect each item in the sample
↓
Accept the lot if: number of defective items ≤ c

EXAMPLE : Inspection of the concentration of *Salmonella* in fresh vegetables

- Description of an ICMSF plan :

n = 5 = number of items of 25 g in the sample
m = maximum content admitted in *Salmonella* per item = 0 CFU in 25 g
c = 0 = maximum number of items of the sample where the concentration x in *Salmonella* is higher than m (i.e. *Salmonella* is detected).

The lot is accepted if no item in the sample shows a concentration greater than m. The lot is rejected in the opposite case.

- Result of the inspection :

The measures of concentration in the sample are the following :

x_1 = Salmonella detected
$x_2 = 0$
$x_3 = 0$
$x_4 = 0$
$x_5 = 0$

There is one item where *Salmonella* was detected (i.e. whose concentration in *Salmonella* is greater than m), the lot is therefore rejected.

3.2.2 Three-class Attributes Plans[17]

Three class attributes plans are defined by the values n, c, m and M (see below); and are applied to situations where the *quality of the product can be divided into three attribute classes* depending upon the concentration of micro-organisms within the sample:

- unacceptable quality, with a concentration of micro-organisms above the value, M (which must not be exceeded by any items in the sample).
- good quality, where the concentration must not exceed the value, m.
- marginally acceptable quality, there marginal items have a concentration which exceeds m, but which is less than M (such concentrations are undesirable but some can be accepted, the number acceptable being denoted by c).

The value m is the concentration of the micro-organism which is acceptable and attainable in the food under inspection, as reflected by Good Commercial Practice (GCP). For 3-class plans, m will usually be assigned a non-zero value.

The value M is a hazardous or unacceptable level of contamination caused by poor hygienic practice, including improper storage. There are several approaches to choosing the value of M:

(i) as a 'utility' (spoilage or shelf-life) index, relating levels of contamination to detectable spoilage (odour, flavour) or to an unacceptably short shelf-life;
(ii) as a general hygiene indicator, relating levels of the indicator contaminant to a clearly unacceptable condition of hygiene;
(iii) as a health hazard, relating contamination levels to illness. A variety of data may be used for this purpose including, for example, epidemiological, experimental animal feeding and human feeding data.

The values m and M may be independent of each other.

The choice of values for n and c varies with the desired stringency (probability of rejection). For stringent

[17] For non homogenous lots (especially the ones where the distribution of the characteristic shows several peaks), a punctual or a stratified sampling plan should be performed.

'cases', n is high and c is low; for lenient 'cases' n is low and c is high. The choice of n is usually a compromise between what is an ideal probability of assurance of consumer safety and the work load the laboratory can handle.

The probabilities of acceptance (P_a) of lots containing selected percentages of defective items (P_d; defective rate in the lot, i.e. lots for whose the concentration in micro-organisms is greater than M) and marginally acceptable items (P_m; marginal rate in the lot, i.e. lots for whose the concentration in micro-organisms lies between m and M),

n is the number of items in the sample
c is the maximum number allowed of marginal items.

If the concentration of micro-organisms in any item of the sample is greater than M, the lot is directly rejected.

The equation of the OC curve of such plans is the following :

$$P_a = \sum_{i=0}^{i=c} C_n^i \left(\frac{P_m}{100}\right)^i \left(\frac{100 - P_d - P_m}{100}\right)^{n-i}$$

Summary of three-class attributes sampling plans

Set the values of m, M, n ,c

⬇

Collect the sample with n items

⬇

Inspect each item in the sample

⬇

Accept the lot if: number of marginally defective items (i.e. a concentration of micro-organisms between m and M) ≤ c

Immediately reject the lot if the concentration of micro-organisms in any item > M

EXAMPLE : Inspection of the concentration of mesophilic aerobic micro-organisms in fresh vegetable

- Description of an ICSMF plan :

n = 5 = the number of items in the sample
m = 10^6 CFU/g
M = 5 10^6 CFU/g
c = 2 = the maximum number allowed of items in the sample whose concentration in mesophilic aerobic micro-organisms lies between m and M
.

The lot is accepted if no item shows a concentration greater than M and if the maximum number of items in the sample whose concentration lies between m and M, is at most equal to c.

- Result of the inspection

The measures of concentration in the sample are the following :

$x_1 = 2.\ 10^7$
$x_2 = 2.10^6$
$x_3 = 2.\ 10^7$
$x_4 = 2.10^6$
$x_5 = 2.10^6$

There are 3 items of the sample whose concentration in mesophilic aerobic micro-organisms lies between m and M, this figure is greater than c and the lot is rejected.

3.2.3 The Application of Two and Three-class Attributes Plans

Two and three-class attributes plans are ideally suited for regulatory, port-of-entry, and other consumer-oriented situations where little information is available concerning the microbiological history of the lot. The plans are independent of lot size if the lot is large in comparison to sample size. The relationship between sample size and lot size only becomes significant when the sample size approaches one tenth of the lot size, a situation rarely occurring in the bacteriological inspection of foods.

When choosing a plan one must consider: (i) the type and seriousness of hazards implied by the micro-organisms; and (ii) the conditions under which the food is expected to be handled and consumed after sampling. Table 10 of the ICMSF publication classifies 15 different 'cases' of sampling plans taking these factors into consideration, the stringency of the plans increasing with the type and degree of hazard. Case 1 requires the most lenient plan whereas Case 15 represents the most stringent requirement. In Table10, a sampling plan is recommended for each of the 15 'cases'.

EXAMPLES :

(i) A sampling plan is required for the inspection of fresh or frozen fish for the bacterium *Escherichia coli*. The contamination of fish with *E. coli* is considered (1) to be a low indirect health hazard which is likely to be reduced during the handling of the fish. Normally the fish will be cooked before consumption. Consequently, the contamination of fish with E. coli may be classified as Case 4 in Table 10 and the recommended sampling plan is a 3-class attributes plan, where n = 5 and c = 3. (The values of m and M will also be specified.)

(ii) The contamination of cooked crabmeat with *Staphylococcus aureus* is considered (1) to be a moderate direct health hazard of limited spread which is likely to increase with handling (Case 9). Consequently, the appropriate sampling plan for the inspection of *S. aureus* in cooked crabmeat is a 3-class plan where n = 10 and c = 1. (The values of m and M will also be specified.)

(iii) The contamination of frozen, ready-to-eat, bakery products (with low-acid or high water activity fillings or toppings) with *Salmonella* is considered to be a moderate direct health hazard of potentially extensive spread in food which is likely to increase with handling (Case 12). In this example, the appropriate plan is a 2-class plan where n = 20 and c = 0.

SECTION 4: THE SELECTION OF SAMPLING PLANS FOR A CONTINUOUS SERIES OF LOTS FROM A SINGLE SOURCE

4.1 PRESENTATION OF SECTION 4

Normally, the sampling plans described in Sections 4.2 and 4.3 should only be applied to a continuous series of lots from a single source. However, the plans described below (including the switching rules) may be utilised when data have been collected describing the quality of isolated lots, from a single source, over a prolonged period of time.

This section addresses the selection of single sampling plans for inspection of percent nonconforming, for a continuing series of lots coming from a single source.

It recommends single sampling plans by attributes (section 4.2) and by variables (section 4.3) with their characteristics:

- Number of items in the sample,
- Acceptable Quality Level (AQL),
- for attributes plans: acceptance number c, i.e. the maximum number of nonconforming items in the sample,
- for variables plans, the acceptance constant K to be included in the lot acceptance formula,
- operating characteristic curves.

To make the document readily readable, and to achieve minimum difficulty in implementing the plans and minimum inspection cost, these plans are limited to the following characteristics:

- AQL 0.65%,. 2.5%, , 6.5%
- n, number of items in the sample, included between 2 and 50

Codex Committees and, where applicable, governments, will select from these plans on the basis of the quality aim they set themselves. This quality level is stated by the Acceptable Quality Level.

The lowest level of acceptable quality or LQ derives from the characteristics of the choice of n and of AQL.

Each single sampling plan recommended in section 4 is accompanied by a table giving the plan characteristics (AQL, n = sample size, : c = acceptance number of the lot, in the case of plans by attributes, K = acceptance constant, in the case of plans by variables) and the probability of lot acceptance as a function of the rate of nonconforming items in these lots, particularly the LQ or rate of nonconforming items in lots accepted in 10% of cases. All the plans recommended according to the AQL and the size n of the sample, are also grouped per AQL in a graph like the Figure 5, of the Operating Characteristic (OC) curve, which relates the rate of nonconforming items in an inspected lot and the probability of lot acceptance[18]. The following example illustrates this principle of presentation of recommended plans with tables (Table 7) and graphs (Figure 5) of OC curves for simple sampling plans by attributes, of AQL = 6,5 %, n= 2, c = 0 and n = 50, c = 7.

Defective rates in the lots	**Probability to accept these lots n = 2, c = 0** P_{95} [19]= 2,53% P_{50} [20]=29,3% P_{10} [21] =68,4%	**Probability to accept these lots n = 8, c= 1** P_{95} = 2,64% P_{50} =20% P_{10} = 40,6%	**Probability to accept these lots n = 13, c= 2** P_{95} = 6,63% P_{50} =20% P_{10} = 36%	**Probability to accept these lots n = 20, c= 3** P_{95} = 7,13% P_{50}=18,1% P_{10}= 30,4%	**Probability to accept these lots n = 32, c= 5** P_{95} = 8,5% P_{50} =17,5% P_{10} = 27,1%	**Probability to accept these lots n = 50, c= 7** P_{95} =8,2% P_{50} =15,2% P_{10} = 22,4%
0%	100%	100%	100%	100%	100%	100%
5 %	90,3%	94,3%	97,5%	98,4%		99,7%
6,5%	**87,4%**	**90,9%**	**95,2%**	**96,3%**	**98,4%**	**98,5%**
10 %	81%	81,3%	86,6%	86,7%	90,6%	87,8%
20%	64%	**50%**	**50%**	41,1%	36%	19%
30 %	49%	25,5%	20,2%	10,7%	5,1%	0,7%
40%	36%	10,6%	5,8%	1,6%	0,3%	0%
50%	25%	3,5%	1,1%	0,1%	0%	0%
60 %	16%	0,9%	0,1%	0%	0%	0%
80%	4,0%	0%	0%	0%	0%	0%
90%	1%	0%	0%	0%	0%	0%
100%	0%	0%	0%	0%	0%	0%

TABLE 7[22]

Figure 5 gathers the OC curves of these plans by attributes, fixed by the Standard ISO 2859-1.

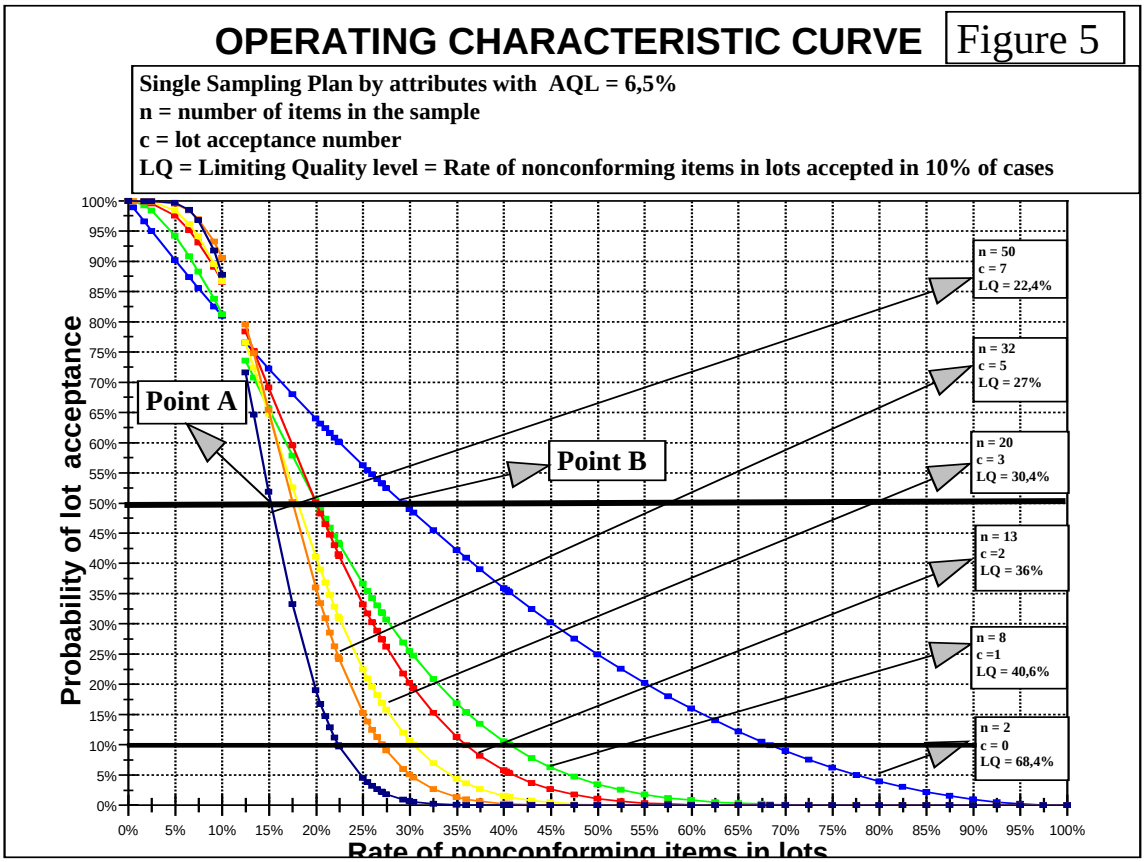
[18] The coordinator of the Drafting Group proposes, per AQL, one graph and one table. If the Drafting Group considers that it is necessary to maintain only one of them, the coordinator would prefer the graph.

[19] P_{95} = Rate of non-conforming items in lots accepted in 95% of cases

[20] P_{50} = Rate of non-conforming items in lots accepted in 50% of cases

[21] P_{10} = Rate of non-conforming items in lots accepted in 10% of cases

[22] The empty boxes of the table correspond to values which have not been calculated, given their limited interest for the user.



Rate of nonconforming items in lots

Figure 5

The curve of Figure 5, which contains the point A, corresponds to a lot inspected with a 50-item sample. The lot is accepted at inspection if there are less than 7 defective items in the sample. The abscissa of the point A (15 %) corresponds to a lot containing 15 % of defective items, its ordinate (50 %) corresponds to the probability to accept these lots containing 15 % of defective items.

The curve of Figure 5, which contains the point B, corresponds to a lot inspected with a 2-item sample. The lot is accepted at inspection if there are less than 0 defective items in the sample. The abscissa of the point B (30 %) corresponds to a lot containing 30 % of defective items, its ordinate (50 %) corresponds to the probability to accept these lots containing 30 % of defective items.

This graph shows that the larger the size of the sample, the lower the risk for the consumer[23] to accept lots having high defective rates.

4.2 SIMPLE SAMPLING PLANS RECOMMENDED FOR INSPECTION OF DEFECTIVE PERCENTAGE BY ATTRIBUTES (FROM ISO 2859-1 : 1989)

4.2.1 General

This ISO Standard presents a sampling system indexed by lot-size ranges, inspection levels and AQLs and specifies sampling plans and procedures for inspection by attributes of discrete items. It especially contains plans for single sampling. It is intended for use as a system employing tightened, normal and reduced inspection on a continuing series of lots, to achieve customer protection while assuring the producer that, if quality is better than the AQL, acceptance will occur most of the time.

[23] The consumer risk generally corresponds to the LQ, defective rate in the lots accepted in 10 % of the cases.

If the standard is applied to the evaluation of **lots in isolation**, it is essential that the user consults the operating characteristic curves in order to identify a plan which offers the desired consumer protection. The objective of ISO 2859-1 is to induce the supplier, through economic and psychological pressure of potential non-acceptance, to maintain a process average quality at least as good as the specified AQL, and to simultaneously provide appropriate consumer protection.

The continuing series of lots should be of sufficient duration to allow the switching rules to be applied. These rules provide for the following:

(i) an automatic protection to the consumer (by means of a switch to tightened inspection or to discontinuation of inspection) in the event that an apparent deterioration of quality is detected;

(ii) an incentive to reduce inspection costs (by means of a switch to reduced inspection, at the discretion of a responsible authority) if consistently good quality is being achieved.

Each lot submitted for evaluation should, as far as is practicable, consist of items of a single type, grade, class, size and composition, produced under essentially the same conditions and at essentially the same time.

The AQL and the inspection level required should be set by the responsible authority. AQL values of 10 or less may be expressed either in per cent nonconforming or in nonconformities per 100 units. However, AQLs in excess of 10 should be expressed in nonconformities per 100 units only. Unless otherwise specified, inspection level II should be used.

The application of ISO 2859-1 attributes sampling plans may be summarised as follows:

Summary of sampling plans by attributes

Set inspection level
(normal[24], tightened, reduced)
↓
Set the AQL
↓
Select sample size, n of the ample and the acceptance number, c and collect the sample
↓
Inspect each item in the sample and enumerate each nonconforming item in the sample
↓
Accept the lot if this number of nonconforming items ≤ Ac

4.2.2 Recommended plans by attributes

This document recommends the following simple sampling plans, a for covering frequent inspection situations. They are extracted from the Standard ISO 2859-1, and are characterised by their AQL, the size n of items in the sample and c the acceptance criterion which defines the maximum number of defective items allowed in the sample for accepting the lot. Each plan is accompanied by a table which gives the probability to accept the lots in function of the defective rate in these lots. For each AQL, a graph sums up the OC curves of the corresponding recommended plans.

The OC curves have been built point-by-point from the following equation :

$$P_A = P\,[x \leq c] = \sum_{i=0}^{i=c} C_n^i p^i (1-p)^{n-i}$$

Where :
P_A = probability to accept the lot
p = defective rate in the lot
i and x are discrete whole variables, between 0 and c

[24] Any inspection level other than the normal control shall be justified by the users of sampling plans.

$$C_n^i = \frac{n!}{i!(n-i)!}$$

Table 8 indicates the correspondence between the letter-code of the sample size in ISO 2859-1 and the sample size in the case of a normal inspection.

Letter-code of sample size	Size of sample n
A	2
B	3
C	5
D	8
E	13
F	20
G	32
H	50

Table 8

4.2.2.1 Plans with AQL = 0,65 % (see Table 9 and Figure 6)

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code F, AQL = 0,65%, n= 20, c =0
0%	100%
0,05%	99%
0,25%	95%
0,525%	90%
0,65%	87,8%
1,43%	75%
3,41%	50%
5%	35,8%
6,7%	25%
10%	12,2%
10,9%	10%
13,9%	5%
15%	3,9%
20%	1,2%
20,6%	1%
30%	0,1%
35%	0%
100%	0%

TABLE 9

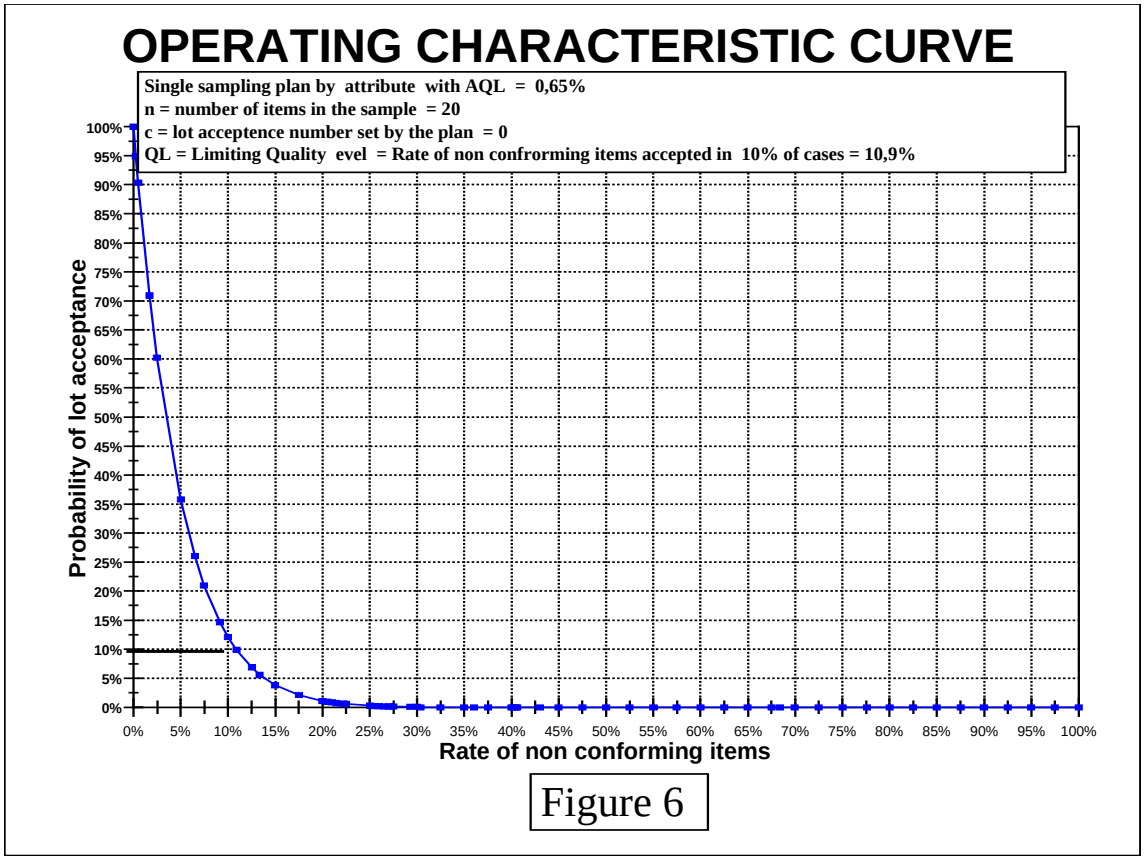


Figure 6

FIGURE 6

4.2.2.2 PLANS WITH AQL = 2,5% (see Table 10 and figure 7)

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code C, AQL = 2,5%, n= 5, c =0 P_{95} = 1,02% P_{50} =12,2% P_{10} = 36,9%	Probability to accept these lots : Normal inspection plan Letter-code F, AQL = 2,5%, n= 20, c =1 P_{95} = 1,8% P_{50} =8,25% P_{10} = 18,1%	Probability to accept these lots : Normal inspection plan Letter-code G, AQL = 2,5%, n= 32, c =2 P_{95} = 2,59% P_{50} =8,25% P_{10} = 15,8%	Probability to accept these lots : Normal inspection plan Letter-code H, AQL = 2,5%, n= 50, c =3 P_{95} = 2,77% P_{50} =7,29% P_{10} = 12,9%
0%	100%	100%	100%	100%
1%	95%	98,3%	99,6%	99,8%
2,5%	88,1%	91,2%	95,5%	96,4%
5%	77,4%	73,6%	78,6%	76%
10%	59%	39,2%	36,7%	25%
15%	44,4%	17,6%	12,2%	4,6%
20%	32,8%	6,9%	3,2%	0,6%
30%	16,8%	0,8%	0,1%	0%
40%	7,8%	0,1%	0%	0%
50%	3,1%	0%	0%	0%
[2]100%	0%	0%	0%	0%

TABLE 10

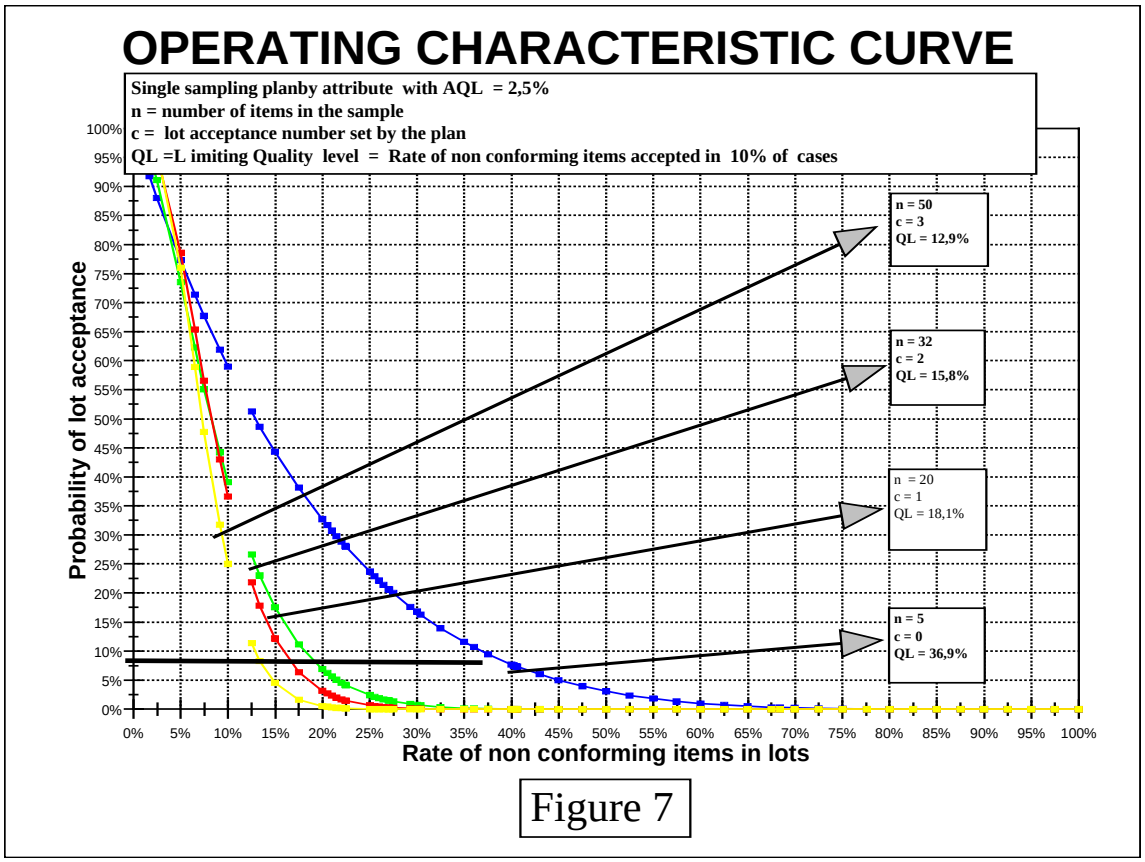


Figure 7

FIGURE 7

4.2.2.3 PLANS AT AQL = 6,5 % (see table 11 and figure 8)

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code A, AQL=6,5% n= 2, c =0 P_{95} [25]= 2,53% P_{50} [26]=29,3% P_{10}[27] =68,4%	Probability to accept these lots : Normal inspection plan Letter-code D, AQL =6,5% n= 8, c =1 P_{95} = 2,64% P_{50} =20% P_{10} = 40,6%	Probability to accept these lots : Normal inspection plan Letter-code E, AQL =6,5% N= 13, c =2 P_{95} = 6,63% P_{50} =20% P_{10} = 36%	Probability to accept these lots : Normal inspection plan Letter-code F, AQL =6,5% n= 20, c =3 P_{95} = 7,13% P_{50}=18,1% P_{10}= 30,4%	Probability to accept these lots : Normal inspection plan Letter-code G, AQL =6,5% n= 32, c =5 P_{95} = 8,5% P_{50} =17,5% P_{10} = 27,1%	Probability to accept these lots : Normal inspection plan Letter-code H, AQL =6,5% n= 50, c =7 P_{95} =8,2% P_{50} =15,2% P_{10} = 22,4%
0%	100%	100%	100%	100%	100%	100%
5 %	90,3%	94,3%	97,5%	98,4%		99,7%
6,5%	**87,4%**	**90,9%**	**95,2%**	**96,3%**	**98,4%**	**98,5%**
10 %	81%	81,3%	86,6%	86,7%	90,6%	87,8%
20%	64%	**50%**	**50%**	41,1%	36%	19%
30 %	49%	25,5%	20,2%	10,7%	5,1%	0,7%
40%	36%	10,6%	5,8%	1,6%	0,3%	0%
50%	25%	3,5%	1,1%	0,1%	0%	0%
60 %	16%	0,9%	0,1%	0%	0%	0%
80%	4,0%	0%	0%	0%	0%	0%
90%	1%	0%	0%	0%	0%	0%
100%	0%	0%	0%	0%	0%	0%

TABLE 11

[25] P_{95} = Rate of non-conforming items in lots accepted in 95% of cases

[26] P_{50} = Rate of non-conforming items in lots accepted in 50% of cases

[27] P_{10} = Rate of non-conforming items in lots accepted in 10% of cases

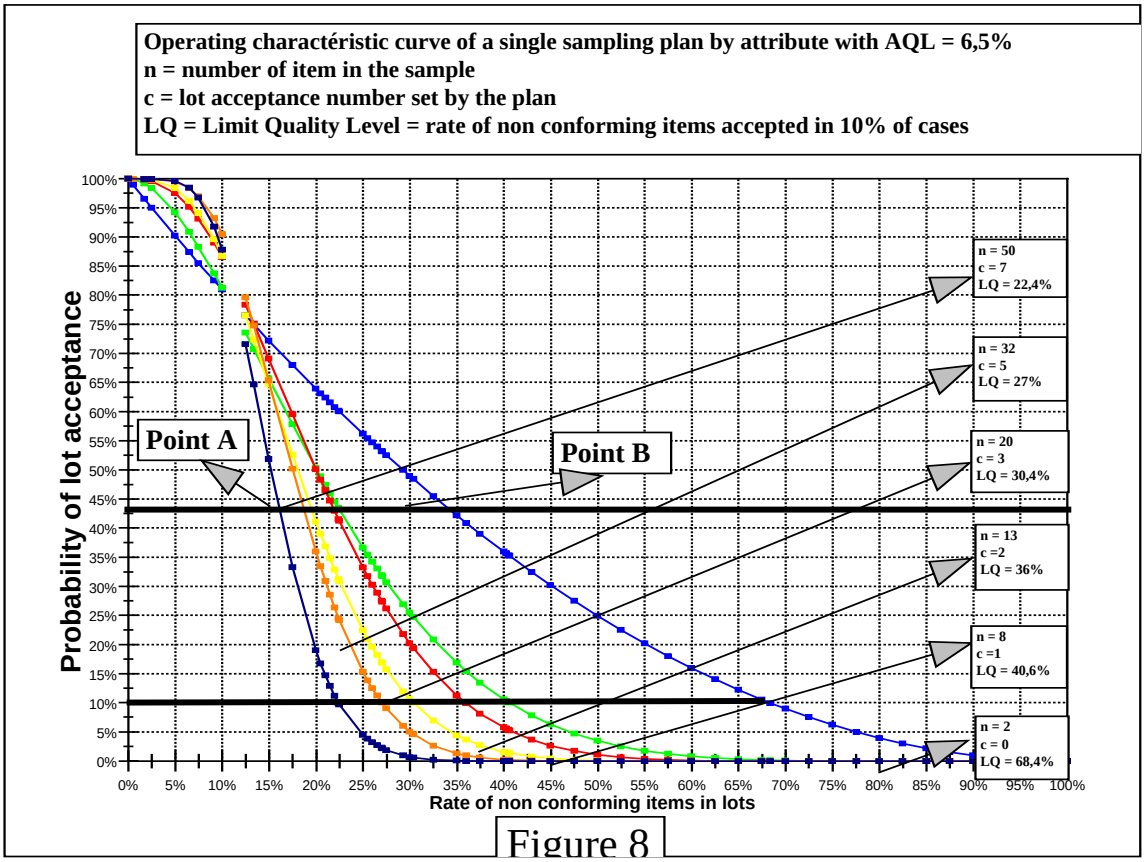


FIGURE 8

4.2.2.4 Switching Rules and Procedures (see clause 9.3; ISO 2859-1:1989(E))

Tightened Inspection

When normal inspection is being performed, tightened inspection must be introduced when two out of five, or less, consecutive lots have been non-acceptable on original inspection (ignoring resubmitted lots). Normal inspection can only be restored when five successive lots have been accepted under tightened inspection.

When operating under tightened inspection, an appropriate sampling plan is selected using the procedure described in Section 4.1, excepting that Table II-B in ISO 2859-1: 1989 (E) is used for the selection of n and Ac. In general, a tightened plan has the same sample size as the corresponding normal plan but a smaller acceptance number. However, if the normal inspection acceptance number is 1 or 0, tightening is achieved by retaining the acceptance number whilst increasing the sample size.

Reduced Inspection

When normal inspection is being performed, reduced inspection may be operated provided that each of the following conditions is satisfied:

(a) the preceding 10 lots (or more) have been subjected to normal inspection and all have been accepted on original inspection; and

(b) the total number of nonconforming units (or nonconformities) in the samples from the preceding 10 lots (or such other number as was used for condition (a), above) is equal to or less than the appropriate 'limit number' given in Table VIII in ISO 2859-1: 1989 (E); and

(c) production is at a 'steady state' (i.e. there has not been a break in production sufficient to invalidate the argument that the present quality is good because the record of the recent past is good, and that all factors which are likely to effect the quality of the product have remained consistent); and

(d) reduced inspection is considered desirable by the responsible authority.

In these circumstances, the inspection costs may be reduced by using reduced-inspection sampling plans which, typically, have sample sizes only two-fifths the size of the corresponding normal inspection plans.

When operating under reduced inspection, an appropriate sampling plan is selected using the procedure described in Section 4.1, excepting that Table II-C in ISO 2859-1: 1989 (E)is used for the selection of n and Ac.

Normal inspection should be reverted to if a lot is not accepted on reduced inspection; or if production becomes irregular or delayed; or if other conditions occur which are likely to invalidate the steady-state condition.

Discontinuation of Inspection

Once tightened inspection has been introduced, the acceptance procedures of ISO 2859 should be discontinued if five, or more, lots are not accepted. Inspection should not resume until the responsible authority is satisfied that the producer has taken the necessary action to improve the quality of the submitted product. Tightened inspection should then be used as described above.

The switching rules described above are illustrated schematically in Figure 5.

4.3 SINGLE SAMPLING PLANS RECOMMENDED FOR INSPECTION BY VARIABLES FOR PER CENT NONCONFORMING

(see ISO 3951: 1989 (E))

4.3.1 General

This Standard presents a sampling system indexed by lot size ranges, inspection levels and AQLs, and is complementary to ISO 2859-1. ISO 3951 is intended primarily for *the inspection of a continuing series of lots, from one source, of sufficient duration to allow the switching rules to operate.* The Standard should be applied, separately, to each producer when products are received from more than one source.

It is only applicable where a single quality characteristic, measurable on a continuous scale, is considered. If several quality characteristics are considered to be important, this standard should be applied to each one separately. The quality characteristic should be distributed according to a normal distribution or to a distribution closely approximating normality. (A set of measurements can often be converted from a non-normal to a normal, or near normal, distribution by a simple mathematical transformation, such as taking the logarithm or square root.) A lot is judged as unacceptable when the distribution of the characteristic fails to indicate an average and variability which meets the sampling criteria for the single or double specification limits prescribed. A product is classified as nonconforming when the measured quality characteristic, x, satisfies one of the following inequalities (cases):

$$x > U \qquad (1)$$

$$x < L \qquad (2)$$

$$\text{either } x > U \text{ or } x < L \qquad (3)$$

where, U = the upper specification limit, and
L = the lower specification limit

Cases (1) and (2) have a *single* specification limit, whereas case (3) has a *double* specification limit.

Two methods are used to determine the acceptability of a lot: the **'s' method** (used when the process standard deviation, σ, is *unknown*; and the **'σ' method** (used when the process standard deviation is *known*).

When called for, switching to tightened inspection, or the discontinuation of inspection, is obligatory. However, switching to reduced inspection, when the average process quality is stable at a level below the AQL, is optional and is performed at the discretion of the responsible authority. For example, if there is sufficient evidence from the control charts that the variability is under statistical control, consideration should be given to switching from the 's' method to the 'σ'method, using the consistent value of s as the value for σ.

The application of ISO 3951 variables sampling plans may be summarised as follows:

Summary of variable sampling plans

↓

Select the 's' method (standard deviation unknown) or
the 'σ' method (standard deviation is stable and known)

↓

Set inspection level
(normal, tightened, reduced)

↓

Set the AQL

↓

Select sample size, n & acceptability constant, k and collect sample

↓

Measure the characteristic x in each item in the sample

4.3.1.1 Decision rule for the 's' method (see table 4)

(a) calculate the sample mean, $\bar{x}$, and

(b) calculate the estimated standard deviation, s = $\sqrt{\sum_{i=1}^{i=n} \frac{\left(x_i - \bar{x}\right)^2}{n-1}}$

(c) see table 4.

4.3.1.2 Decision rules for the 'σ' method (see table 3)

(This method should only be used when there is valid evidence that the standard deviation of the process can be considered constant and taken to be 'σ')

a) calculate the mean of the sample $\bar{x}$
b) consult table 3

4.3.2 Recommended sampling plans by variables : s method

4.3.2.1 General

This section recommends the following simple sampling plans, a for covering frequent inspection situations. They are extracted from the Standard ISO 3951, and are characterised by their AQL, the size n of items in the sample and K the acceptance constant. Each plan is accompanied by a table which gives the probability to accept the lots in function of the defective rate in these lots. For each AQL, a graph sums up the OC curves of the corresponding recommended plans.

The OC curves have been built point-by-point from the tables of values of ISO 3951.

Table 12 indicates the correspondence between the letter-code of the sample size in ISO 3951 and the sample size in the case of a normal inspection.

Letter-Code of sample size	Size n of sample
D	5
E	7
F	10
G	15
H	20
I	25
J	35
K	50

TABLE 12

4.3.2.2 Plans at AQL = 0,65 % (see table 13 and figures 9 & 10)

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code D, AQL = 0,65%, n= 5, K =1,65	Probability to accept these lots : Normal inspection plan Letter-code E, AQL = 0,65%, n= 7, K =1,75	Probability to accept these lots : Normal inspection plan Letter-code F, AQL = 0,65%, n= 10, K =1,84	Probability to accept these lots : Normal inspection plan Letter-code G, AQL = 0,65%, n= 15, K =1,91
0%	100%	100%	100%	100%
1%	84%	88%	84%	84%
1,5%				75%
1,61%			75%	
1,83%		75%		
2%	76%	74%	70%	66%
2,15%	75%			
3%	68%	64%	58%	52%
3,09%				50%
3,77%			50%	
4,83%		50%		
5%	56%		40%	76%
6,3%	50%			
7%	46%	38%	28%	18%
7,72%			25%	
8%	42%	34%	24%	14%
9%	40%	30%	20%	11%
9,41%				10%
10%	36%	26%	36,7%	8%
13,23%			10%	
14,64%	25%			
15%	24%	15%	7,5%	2%
17,47%			5%	
18,6%		10%		1%
20%	16%	8%	4%	0%
25%	10,4%	5%		0%
25,9%	10%			0%
27,19%			1%	0%
30%	7%		0%	0%
34%	5%		0%	0%
37,8%		1%	0%	0%
40%	3%	0%	0%	0%
45%	2%	0%	0%	0%
50%	1%	0%	0%	0%
60,2%	1%	0%	0%	0%
75%	0,1%	0%	0%	0%
100%	0%	0%	0%	0%

TABLE 13

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code H, AQL = 0,65%, n= 20, K =1,96	Probability to accept these lots : Normal inspection plan Letter-code I, AQL = 0,65%, n= 25, K =1,98	Probability to accept these lots : Normal inspection plan Letter-code J, AQL = 0,65%, n= 35, K =2,03	Probability to accept these lots : Normal inspection plan Letter-code K, AQL = 0,65%, n= 50, K =2,08
0%	100%	100%	100%	100%
1%	84%	84%	84%	84%
1,26%				75%
1,34%			75%	
1,42%		75%		
1,61%	75%			
1,94%				50%
2%	63%	62%	56%	48%
2,21%			50%	
2,53%		50%		
2,69%	50%			
2,89%				25%
3%	44%	40%	32%	22%
3,25%			25%	
4%	32%	28%	19%	10%
4,25%		25%		
4,75%	25%			
4,87%				5%
5%	24%	18%		4%
5,10%			10%	
6%	16%	12%	6%	
6,46%		10%		
7%	12%	8%	3,5%	1%
7,46%	10%			
8%	8%	6%	2%	0,5%
9%	6%	4%	1%	
9,54%	5%		0%	0%
10%	4%	2%	0%	0%
14,42%	1%		0%	0%
15%	0%	0%	0%	0%

FOLL. TABLE 13

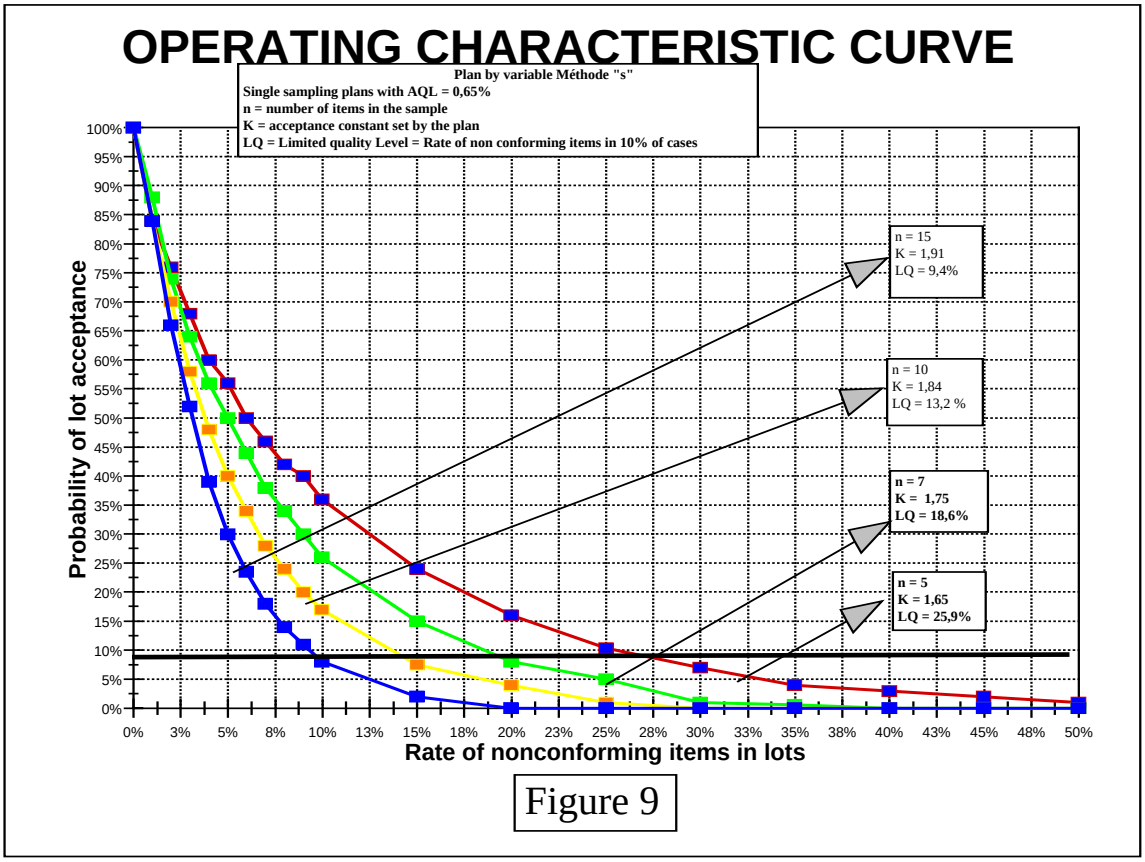


Figure 9

FIGURE 9

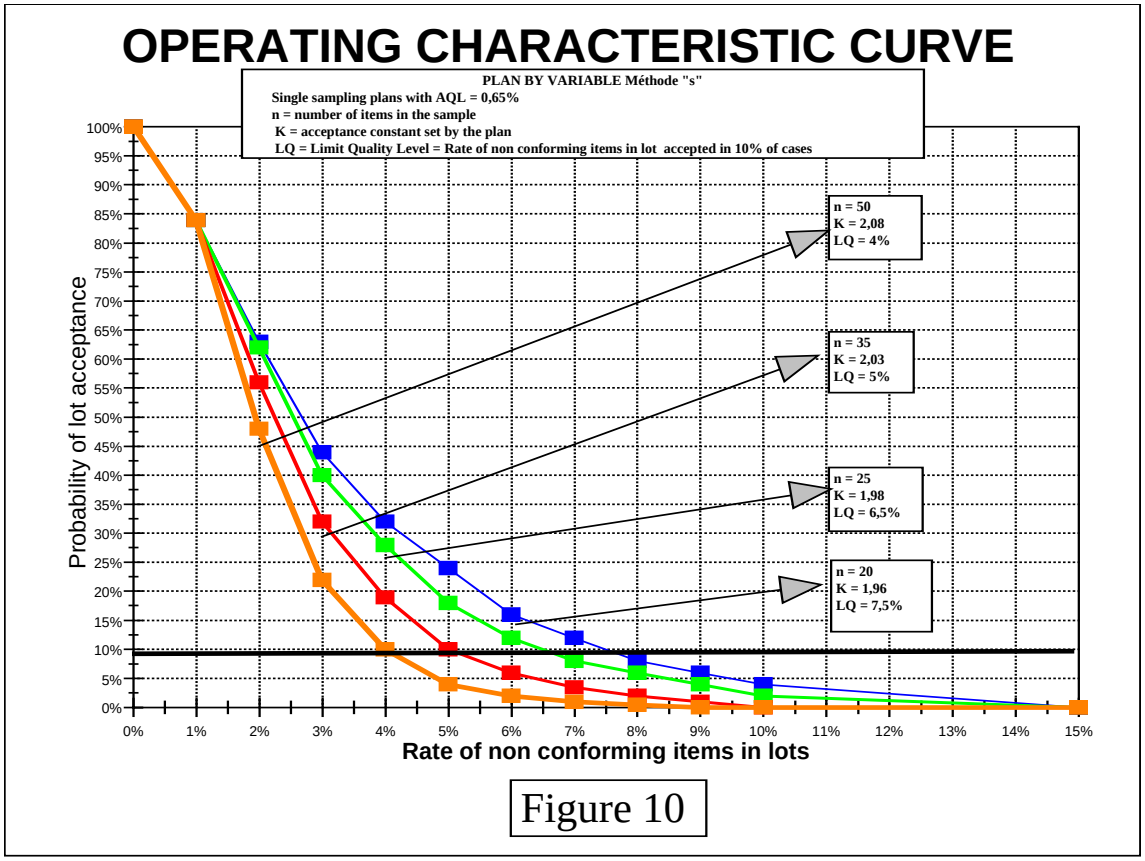


Figure 10

FIGURE 10

4.3.2.3 PLANS AT AQL = 2,5% (see table 14 et figures 11 and 12)

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code D, NQA = 2,5%, n= 5, K =1,24	Probability to accept these lots : Normal inspection plan Letter-code E, NQA = 2,5%, N= 7, K =1,33	Probability to accept these lots : Normal inspection plan Letter-code F, NQA = 2,5%, N= 10, K =1,41	Probability to accept these lots : Normal inspection plan Letter-code G, NQA = 2,5%, n= 15, K =1,47
0%	100%	100%	100%	100%
1%	96%	96%	97,5%	99%
2%	94%	94%	92,5%	95%
3%	86%	86%	86%	86%
4%	82%	82%	80%	78%
4,5%				75%
4,7%			75%	
5%	78%	76%	73%	70%
5,25%		75%		
5,78%	75%			
6%	74%	70%	66%	62%
7%	69%	66%	59%	54%
7,5%				50%
8%	66%	60%	54%	46%
8,62%			50%	
9%	61%	56%	48%	39%
10%	58%	52%	42%	34%
10,28%		50%		
11,77%				25%
12,47%	50%			
14,5%			25%	
15%	42%	34%	23%	14%
16,8%				10%
18,1%		25%		
20%	30%	21%	12%	5%
21,4%			10%	
22,88%	25%			
25%	23%	13%	6%	1,5%
26,27%			5%	
27,43%		10%		
27,88%				1%
30%	15%	8%	2%	0%
33,82%		5%		
35%	10%			0%
36,5%			1%	0%
40%	6%	2%	0%	0%
45%	4%	1%	0%	0%
50%	2%	0%	0%	0%
60%	0,5%	0%	0%	0%

TABLE 14

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code H, AQL = 2,5%, n= 20, K =1,51	Probability to accept these lots : Normal inspection plan Letter-code I, AQL = 2,5%, N= 25, K =1,53	Probability to accept these lots : Normal inspection plan Letter-code J, AQL = 2,5%, N= 35, K =1,57	Probability to accept these lots : Normal inspection plan Letter-code K, AQL = 2,5%, n= 50, K =1,61
0%	100%	100%	100%	100%
1%	99%	99%	99%	99%
2%	95%	94%	94%	98%
2,77%	90%	90%		
3%	88%	88%	90%	90%
4%	78%	78%	75%	75%
4,35%	75%	75%		
5%	68%	66%	62%	58%
5,48%				50%
6%	58%	56%	50%	40%
6,54%		50%		
6,85%	50%			
7%	49%	44%	38%	28%
7,25%				25%
8%	40%	36%	25,5%	18%
9%	32%	28%	20%	11%
9,23%				10%
9,47%		25%		
10%	26%	22,5%	14%	8%
10,29%	25%			
10,85%			10%	
11%	21%	16%		4%
12%	17%	12%	6%	2%
13%	13%	10%	4%	1%
14%	10%	7%	3%	0%
14,25%	10%			0%
15%	8%	5%	0%	0%
17%	5%		0%	0%
20%	2%	1%	0%	0%
23%	1%	0%	0%	0%
25%	0%	0%	0%	0%

FOLL. TABLE14

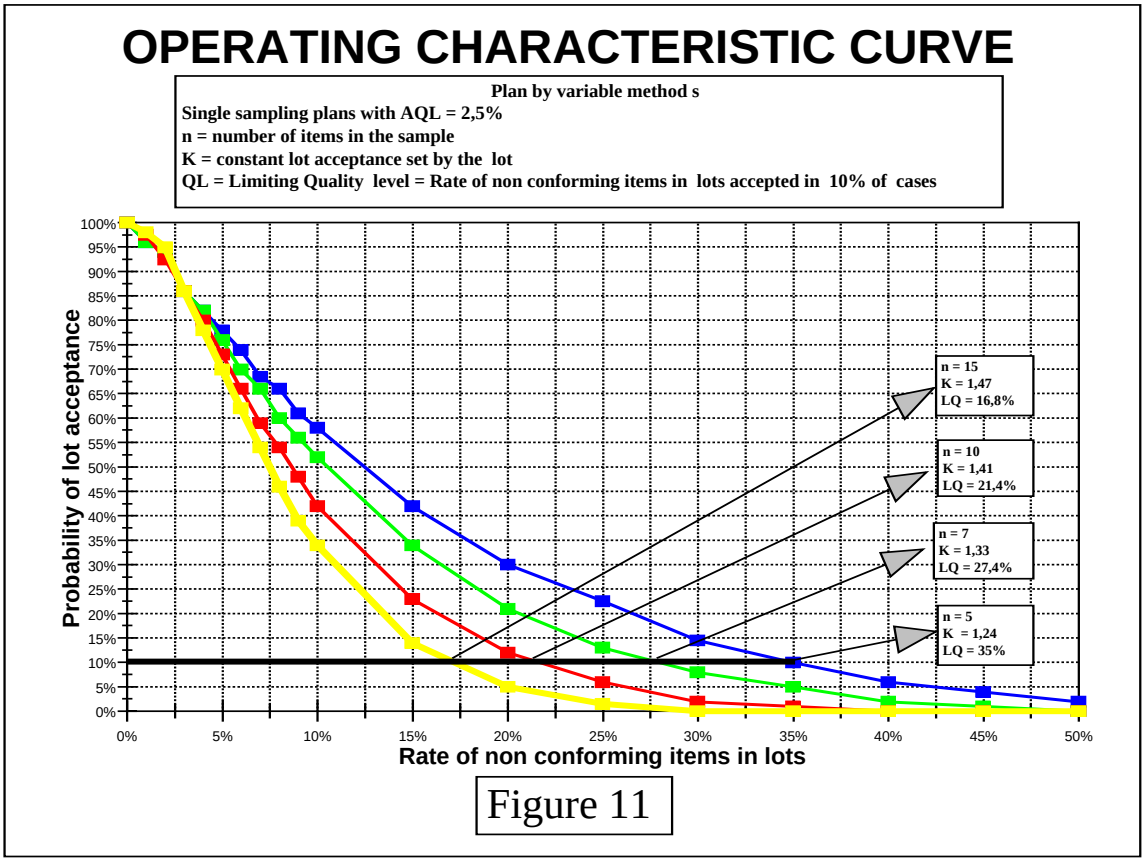


Figure 11

FIGURE 11

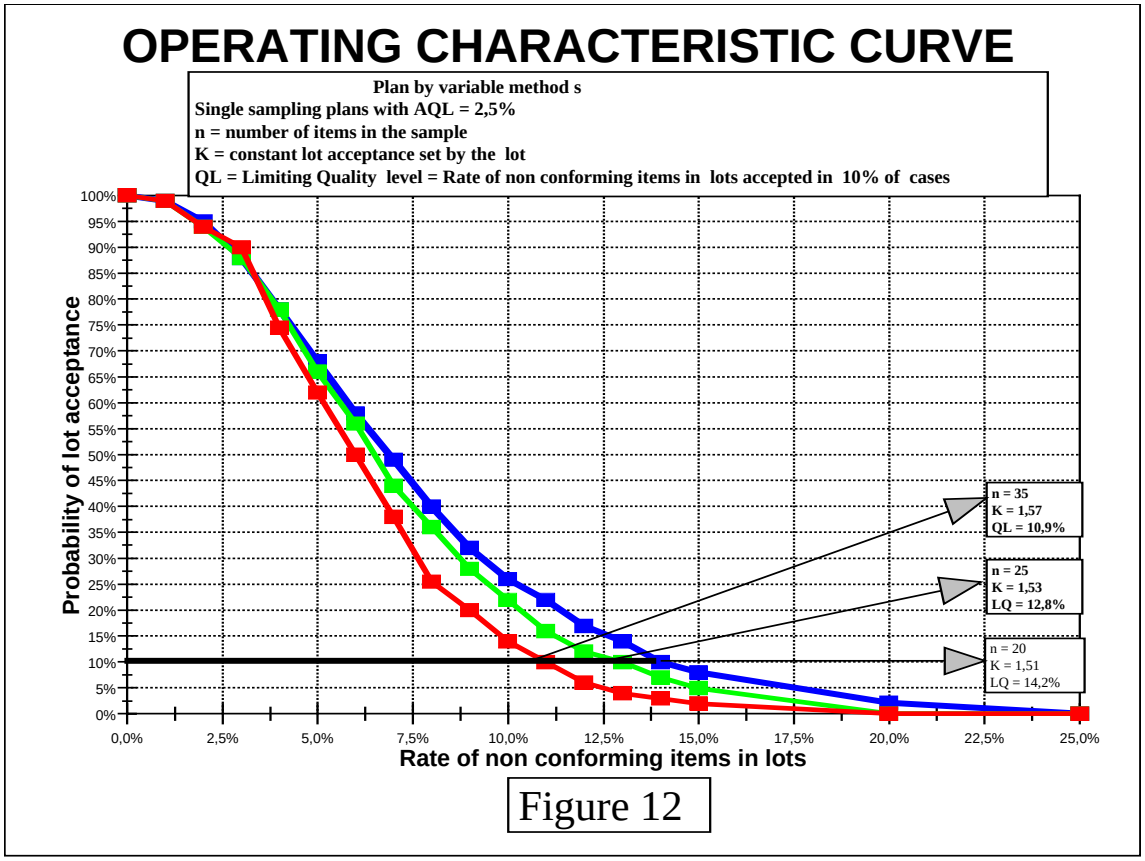


Figure 12

FIGURE 12

4.3.3 **Recommended sampling plans by variables : σ method**

4.3.3.1 General

This document recommends the following simple sampling plans, a for covering frequent inspection situations. They are extracted from the Standard ISO 3951, and are characterised by their AQL, the size n of items in the sample and K the acceptance constant. Each plan is accompanied by a table which gives the probability to accept the lots in function of the defective rate in these lots. For each AQL, a graph sums up the OC curves of the corresponding recommended plans.

The OC curves have been built point-by-point from the following .equation :

$$u_{PA} = \sqrt{n} * (u_{1-p} - K)$$

where :
u_{PA} is the fractile of P_A order of the centered reduced normal law,
P_A is the probability to accept the lot having a defective rate of p
U_{1-p} is the fractile of 1-p order of the centered reduced normal law,
p is the defective rate accepted in the lot with the probability P_A.

Tables 15 and 16 indicate the correspondence between the letter-code of the sample size in ISO 3951 and the sample size in the case of a normal inspection.

Letter Code of sample size	Sample size n
(for AQL = 0,65%)	
E	3
F	4
G	5
H	7
J [28]	11
K	16
L	23
M	30
N	44

TABLE 15

Letter Code of sample size	Sample size n
(for NQA = 2,5%)	
D	3
E	4
F	5
G	7
H	9
I	11
J	15
K	***22***
L	***32***
M	***42***

[28] The plan corresponding to letter I, of poor interest, has been voluntary omitted.

TABLE 16

4.3.3.2 Plans at AQL = 0,65 % (see table 17 and figures 13 and 14)

Defective rates in the lots	**Probability to accept these lots : Normal inspection plan Letter-code E, AQL = 0,65%, n= 3, K =1,69** P_{95} = 0,32% P_{50} =4,55% P_{10} = 18,6%	**Probability to accept these lots : Normal inspection plan Letter-code F, AQL = 0,65%, n= 4, K =1,80** P_{95} = .0,36% P_{50} =3,6% P_{10} = 13,2%	**Probability to accept these lots : Normal inspection plan Letter-code G, AQL = 0,65%, n= 5, K =1,88** P_{95} = 0,45% P_{50} =3% P_{10} = 9,41%	**Probability to accept these lots : Normal inspection plan Letter-code H, AQL = 0,65%, n= 7, K =1,95** P_{95} = .0,49% P_{50} =2;56% P_{10} = 7,46%
0%	100%	100%	100%	100%
1%	86,5%	85,4%	84%	84,1%
2%	73,5%	69,4%	65,1%	60,8%
3%	62,9%	56,4%	**50%**	42,7%
4%	54,2%	46,1%	38,6%	29,9%
5%	46,9%	37,8%	29,9%	20,9%
6%	40,7%	31,2%	23,3%	14,7%
7%	35,5%	25,8%	18,3%	10,4%
8%	31,1%	21,5%	14,4%	7,4%
9%	27,3%	17,9%	11,4%	5,3%
9,6%			**10%**	
10%	24%	15%	9%	3,8%
12,3%		**10%**		
15%	12,9%	15%	2,9%	0,8%
17 %	**10%**	4,5%	1,9%	0,4%
20%	7,1%	2,8%	1%	0%
25%	3,9%	1,2%	0,3%	0%
30%	2,2%	0,5%	0%	0%
35%	1,2%	0,2%	0%	0%
40%	0,6%	0,1%	0%	0%
45%	0,3%	0%	0%	0%
50%	0,2%	0%	0%	0%
60%	0%	0%	0%	0%

TABLE 17

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code J, AQL = 0,65%, n= 11, K =2,01 P_{95} = 0,36% P_{50} =2,22% P_{10} = 5,1%	Probability to accept these lots : Normal inspection plan Letter-code K, AQL = 0,65%, n= 16, K =2,07 P_{95} = 0,64% P_{50} =1,92% P_{10} = 4,03%	Probability to accept these lots : Normal inspection plan Letter-code L, AQL = 0,65%, n= 23, K =2,03 P_{95} = 0,7% P_{50} =1,7% P_{10} = 3,24%	Probability to accept these lots : Normal inspection plan Letter-code M, AQL = 0,65%, n= 30, K =2,14 P_{95} = 0,74% P_{50} =1,6% P_{10} = 2,88%	Probability to accept these lots : Normal inspection plan Letter-code N, AQL = 0,65%, n= 44, K =2,17 P_{95} = 0,77% P_{50} =1,5% P_{10} = 2,36%
0%	100%	100%	100%	100%	100%
0,65%	**94,2%**	**95,1%**	**95,6%**	**97%**	**98,1%**
1%	85,3%	84,7%	83,4%	84,6%	85%
2%	55,8%	47,4%	37,8%	31,8%	22%
3%	33,4%	22,5%	13%	7,8%	2,8%
4%	19,5%	**10%**	4,1%	1,6%	0,3%
5%	11,3%	4,5%	1,3%	0,3%	0%
6%	6,5%	2%	0,4%	0,1%	0%
7%	3,8%	0,9%	0,1%	0%	0%
8%	2,2%	0,4%	0%	0%	0%
9%	1,3%	0,2%	0%	0%	0%
10%	0,8%	0,1%	0%	0%	0%
15%	0,1%	0%	0%	0%	0%
16%	0%	0%	0%	0%	0%

TABLE 17 FOLL.

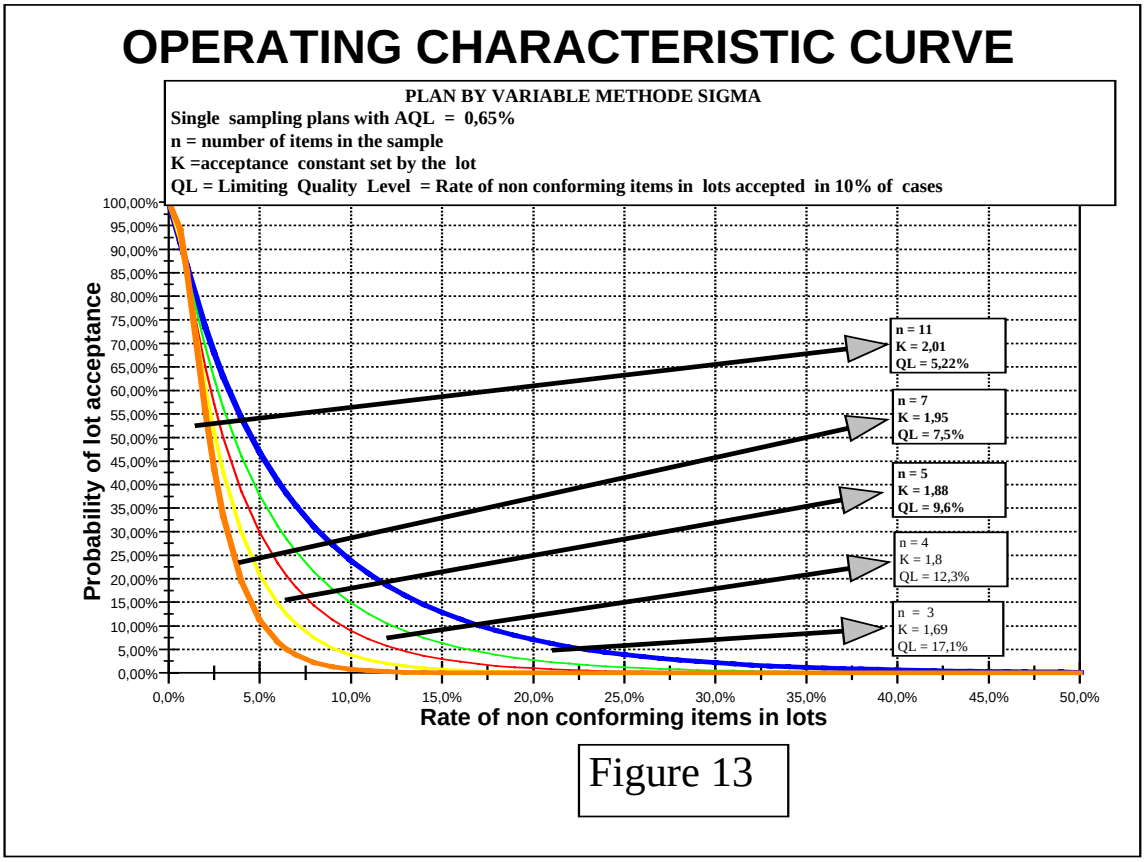


Figure 13

FIGURE 13

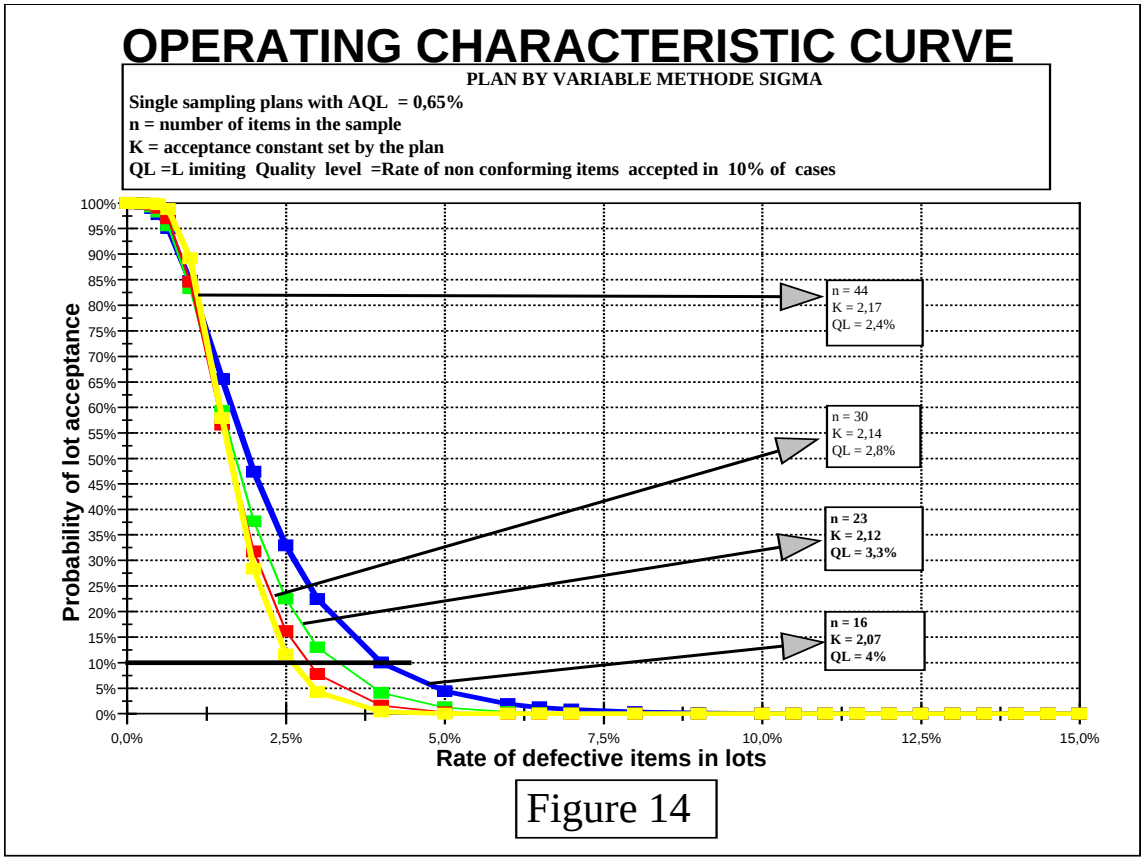


Figure 14

FIGURE 14

4.3.3.3 Plans at AQL = 2,5 % (see Table 18 and figures 15 & 16)

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code D, AQL = 2,5%, n= 3, K =1,17 P_{95} = 1,38% P_{50} =12,1% P_{10} = 35%	Probability to accept these lots : Normal inspection plan Letter-code E, AQL = 2,5%, n= 4, K =1,28 P_{95} = 1,5% P_{50} =10% P_{10} = 27,4%	Probability to accept these lots : Normal inspection plan Letter-code F, AQL = 2,5%, n= 5, K =1,39 P_{95} = 1,65% P_{50} =8,23% P_{10} = 21,4%	Probability to accept these lots : Normal inspection plan Letter-code G, AQL = 2,5%, n= 7, K =1,45 P_{95} = 1,91% P_{50} =7,35% P_{10} = 16,8%	Probability to accept these lots : Normal inspection plan Letter-code H, AQL = 2,5%, n= 9, K =1,49 P_{95} = 2,07% P_{50} =6,81% P_{10} = 14,2%
0%	100%	100%	100%	100%	100%
1%	97,7%	98,2%	98,2%	99%	99,4%
2%	73,5%	93,9%	93,1%	94,5%	95,5%
3%	93,7%	88,5%	86,4%	87,3%	87,9%
4%	84,3%	82,7%	79%	78,7%	78,3%
5%	79,5%	76,7%	71,6%	69,7%	67,9%
6%	74,7%	70,9%	64,4%	60,9%	57,7%
7%	70,2%	65,2%	57,6%	52,7%	48,3%
8%	65,8%	59,9%	51,3%	45,3%	39,9%
10%	57,7%	50%	40,4%	32,8%	26,6%
15%	40,9%	31,3%	21,5%	13,7%	8,7%
20%	28,5%	19%	10%	5,4%	2,6%
25%	19,5%	11,3%	5,5%	2%	0,7%
30%	13,2%	6,5%	2,6%	0,7%	0,2%
35%	8,7%	3,7%	1,2%	0,2%	0%
40%	5,6%	2%	0,6%	0,1%	0%
45%	3,5%	1%	0,2%	0%	0%
50%	2,1%%	0,5%	0,1%	0%	0%
60%	0,7%	0,1%	0%	0%	0%
65%	0,4%	0%	0%	0%	0%
70%	0,2%	0%	0%	0%	0%
75%	0,1%	0%	0%	0%	0%
80%	0%	0%	0%	0%	0%
	0%	0%	0%	0%	0%

TABLE 18

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code I, AQL = 2,5%, n= 11, K =1,51 P_{95} = 2,23% P_{50} =6,55% P_{10} = 12,8%	Probability to accept these lots : Normal inspection plan Letter-code J, AQL = 2,5%, n= 15, K =1,56 P_{95} = 2,38% P_{50} =5,94% P_{10} = 10,8%	Probability to accept these lots : Normal inspection plan Letter-code K, AQL = 2,5%, n= 22, K =1,61 P_{95} = 2,51% P_{50} =5,37% P_{10} = 9,23%	Probability to accept these lots : Normal inspection plan Letter-code L, AQL = 2,5%, n= 32, K =1,65 P_{95} = 2,62% P_{50} =5% P_{10} = 7,82%	Probability to accept these lots : Normal inspection plan Letter-code M, AQL = 2,5% n= 42, K =1,67 P_{95} = 2,73% P_{50} =4,75% P_{10} = 7,11%
0%	100%	100%	100%	100%	100%
1%	99,7%	99,9%	99,9%	99,9%	99,9%
2%	96,4%	97,2%	98,1%	98,3%	99,4%
3%	89,1%	89,3%	89,8%	90,4%	91,4%
4%	78,8%	77%	74,5%	71,6%	69,9%
5%	67,3%	62,9%	56,5%	50%	43,5%
6%	55,9%	49,2%	39,8%	29,5%	22,8%
7%	45%	37,2%	26,5%	16,2%	10%
8%	36,4%	27,4%	16,8%	8,3%	4,3%
9%	28,7%	19,8%	10,3%	4%	1,6%
10%	22,4%	14%	6,2%	1,9%	0,6%
11%	17,4%	10%	3,6%	0,8%	0,2%
13%	10%	4,7%	1,2%	0,2%	0%
15%	5,8%	2,1%	0,4%	0%	0%
20%	1,3%	0,3%	0%	0%	0%
25%	0,3%	0%	0%	0%	0%
30%	0,1%	0%	0%	0%	0%
31%	0%	0%	0%	0%	0%

TABLE 18 FOLL.

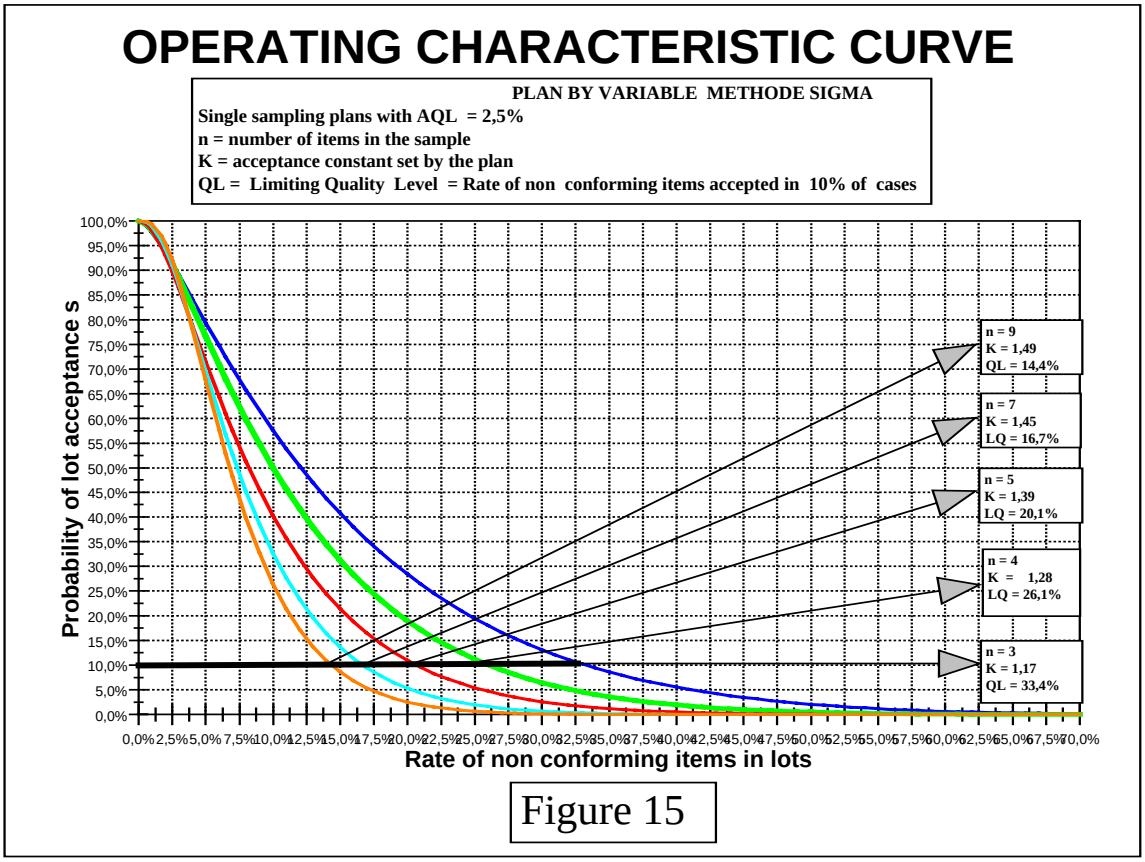


Figure 15

FIGURE 15

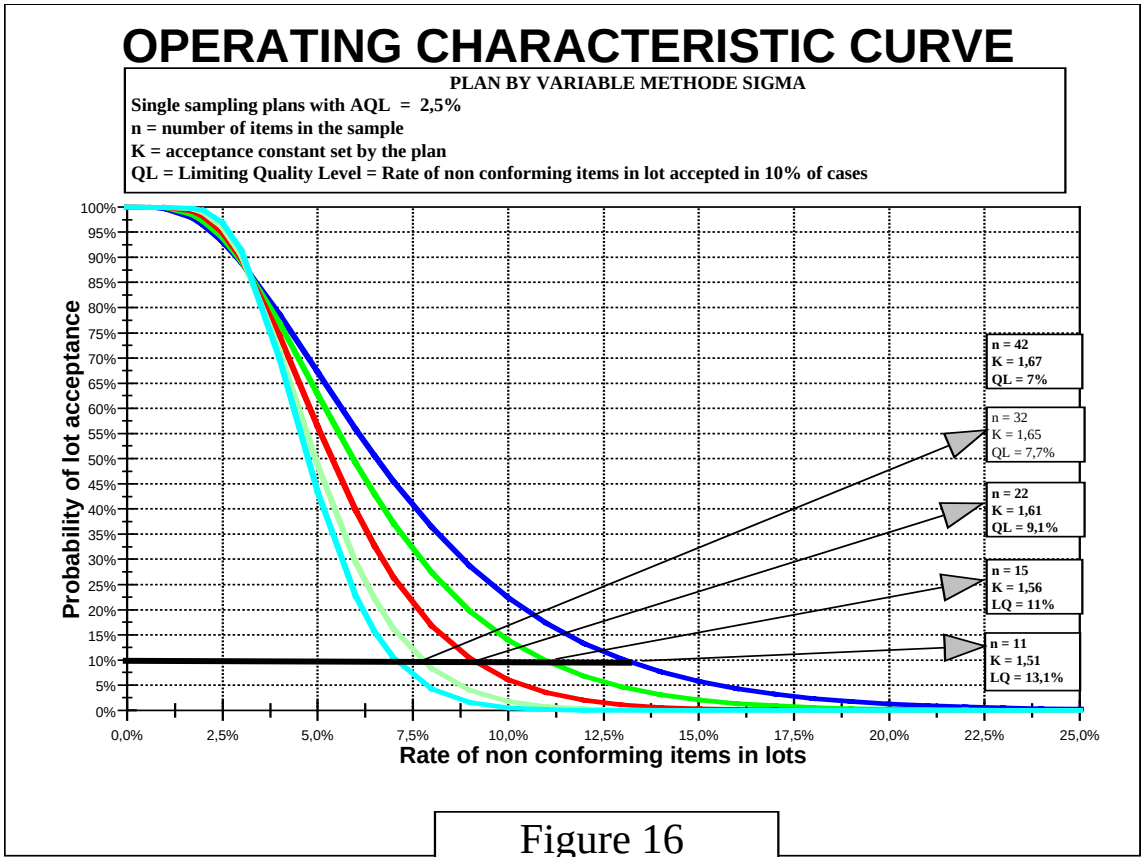


Figure 16

FIGURE 16

4.3.4 Rules and procedures of switching between inspection levels (see article 19 of Standard ISO 3951)

When it is necessary, the switching towards a tightened inspection, or the interruption of the inspection, is mandatory. Nevertheless, the switching toward a reduced inspection, when the mean quality of a process is stable, at a level inferior to the AQL, is optional, at the discretion of the responsible authority. For example, if there are sufficient proofs, from the inspection tables, that the variability is in compliance with the statistical criteria, it can be envisaged to switch from the s method to the σ method, using the value of s instead of σ.

The normal inspection is applied at the beginning of inspection (unless otherwise stated) and shall continue to be applied during inspection till a tightened inspection becomes necessary, or on the contrary, a reduced inspection becomes enough.

A tightened inspection shall be performed when 2 lots submitted to the original normal inspection are not accepted over 5 successive lots. The tightened inspection can be left when 5 successive lots at the first inspection have been accepted at the tightened inspection ; the normal inspection is then again performed.

It is possible to introduce a reduced inspection when 10 successive lots have been accepted at the normal inspection, under the following conditions :

a) these 10 lots would have been accepted if the AQL would have been fixed at the immediately inferior value;
b) the production is under statistical control;
c) the reduced inspection is considered as desirable by the users of the plans;

It is mandatory to stop the reduced inspection and to re-introduce a normal inspection if one of the following conditions are achieved on lots at first inspection :

a) one lot is not accepted;
b) the production is delayed or erratic;
c) other conditions (change of supplier, of workers, of machines,…) imply the need to come back to a normal inspection.

SECTION 5: THE SELECTION OF SAMPLING PLANS FOR THE INSPECTION by variables OF BULK MATERIALS :

Known standard deviation

(see ISO/CD 10725-2.3)

5.1 Generals

Normally, the sampling plans described in Section 5.1 should only be applied to a continuous series of lots from a single source. **However, the plans described below may be utilised** *when data have been collected, describing the standard deviation of the quality characteristic, from isolated lots from a single source, over a prolonged period of time.*

This draft standard addresses the need for sampling plans, by variables, for situations where the estimation of the lot mean of a single quality characteristic is the principal factor in the determination of lot acceptability. It may not always be applicable to situations where the accurate estimation of the lot mean is more important than the determination of lot acceptability. The sampling plans in this standard assume a normal distribution of the quality characteristic. However, users should not be too concerned about a deviation from normality, since the distribution of the sample grand average is usually very close to a normal distribution, unless the sample sizes are too small.

The standard may be applied:

- to *a continuing series of lots*
- to *lots in isolation* (*when the value of each standard deviation of the quality characteristic is considered to be known and stable;* for example, where a lot in isolation with respect to the purchaser may be part of a continuing series of lots produced by the supplier)
- when the specified quality characteristic χ is measurable on a continuos scale
- when the value of each standard deviation of the quality characteristic is known and stable
- to a variety of bulk materials including liquids (where the measurement standard deviation is usually dominant), solids (granular and powdered), emulsions and suspensions
- when a single specification limit is specified (however, under special circumstances, the standard is applicable when double specification limits are specified)

5.2 Standardised sampling procedures for the inspection of individual lots

The standardised sampling procedures for the inspection of individual lots involve the following steps:

Selection of a sampling plan
↓
Drawing of increments from the lot
↓
Preparation of one or more composite samples
↓
Preparation of test samples
↓
Drawing of test portions from the test samples
↓
Measurement of specified quality characteristic of test portions
↓
Determination of lot acceptability

The procedures involved in each step may be summarised as follows:

- **Selection of a sampling plan**
  The selection of a sampling plan involves the following steps:
  - the establishment of *standard deviations, costs, producer's risk quality, consumer's risk quality and discrimination distance*

  Standard deviations

  If both the composite sample standard deviation (S_C) and the test sample standard deviation (S_T) control charts have no 'out of control' points, and if no other evidence gives doubt about their stability, it can be deemed that all standard deviations are stable. Methods for the confirmation and recalculation of standard deviations, including the utilisation of control charts, are provided in clause 12 of ISO/CD 10725-2.3

  Costs

  The total varying cost of the sampling plan per lot consists of the sum of the costs proportional to the total number of increments, to the total number of test samples and to the total number of measurements.

  Producer's risk quality (PRQ)

  The producer's risk quality (m_A) is a lot mean which, in the sampling plan, usually corresponds to a specified producer's risk of approximately 5 per cent.

  Consumer's risk quality (CRQ)

  The consumer's risk quality (m_R) is a lot mean which, in the sampling plan, usually corresponds to a specified consumer's risk of approximately 10 per cent. It is recommended that the distance between the CRQ and the upper (U) or lower (L) specification limit is specified, taking account of the actual use of an accepted lot. When double specification limits are specified, the two distances, between the CRQ and the limits, may be different.

  Discrimination distance

  The discrimination distance (D) is the absolute distance between the PRQ and the CRQ, and should be specified, taking into account the values of the population standard deviations for the increments (σ_I), test samples (σ_P) and measurements (σ_M).

  - the specification of the *acceptance value(s)*

  Acceptance value

  When a lower specification limit is specified, the lower acceptance value is given by the equation:

$$\bar{x}_L = m_A - 0.562D$$

When an upper specification limit is specified, the upper acceptance value is given by the equation:

$$\bar{x}_U = m_A + 0.562D$$

- **Drawing of increments from the lot**

An appropriate sampling device should be used together with representative sampling to afford n_i increments

- **Preparation of one or more composite samples**

The n_i increments are pooled in order to produce n_c composite samples, each of which represent the whole lot. (A recommended, economical procedure is the preparation of *duplicate* samples by combining all odd numbered increments, to produce the first composite sample; and all even numbered increments, to produce the second composite sample.)

- **Preparation of test samples**

n_t test samples, of specified mass and particle size, are prepared from each composite sample, using appropriate crushing/grinding, sample division and mixing procedures.

- **Drawing of test portions**

n_m test portions, of specified mass, are drawn from each test sample

- **Measurement of specified quality characteristic of test portions**

A single measurement is performed on each test portion, to afford $n_c.n_t.n_m$ measurements per lot

- **Determination of lot acceptability**

The sample grand average ($\bar{x}$**)** is calculated form the n_c composite sample averages (which are calculated from the n_T test sample averages which, themselves, are calculated from the n_M measurement results)

° When a single lower specification limit is specified:
Accept the lot if $\bar{x} \geq \bar{x}_L$
Reject the lot if $\bar{x} < \bar{x}_L$

° When a single upper specification limit is specified:
Accept the lot if $\bar{x} \leq \bar{x}_U$
Reject the lot if $\bar{x} > \bar{x}_L$

° When double specification limits are specified:
Accept the lot if $\bar{x}_L \leq \bar{x} \leq \bar{x}_U$
Reject the lot if either, $\bar{x} < \bar{x}_{L,}$ or $\bar{x} > \bar{x}_U$

SECTION 6: REFERENCES

1. Micro-organisms in Foods. 2. Sampling for microbiological analysis: Principles and specific applications; International Commission on Microbiological Specifications for Foods, ICMSF, 1986, ISBN 0-632-015 67-5.

2. Schilling, E G (1978). A Lot Sensitive Sampling Plan for Compliance Testing and Acceptance Sampling. Journal of Quality Technology **10**(2), 47-51.