

# 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-CORRIGENDUM

## 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)

**Insert the following foreword :**

#### FOREWORD

#### INFORMATION FOR CODEX COMMODITY COMMITTEES ON THE SELECTION OF CODEX SAMPLING PROCEDURES AND INTERPRETATION OF CODEX SPECIFICATIONS

#### Introduction and general background

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

Codex Committees should, when developing provisions (characteristics) in a Standard, relate the numerical value of the characteristic, the associated method of sampling and the method of analysis to one another. The Codex General Principles for Analysis and Sampling (Codex Alimentarius Commission, Procedural Manual, Tenth Edition) are intended to ensure that this will be done when selecting Codex methods of sampling and analysis for inclusion in Codex Standards. This requirement is generally followed when methods of analysis are to be developed but, regrettably, infrequently when methods of sampling are to be elaborated.

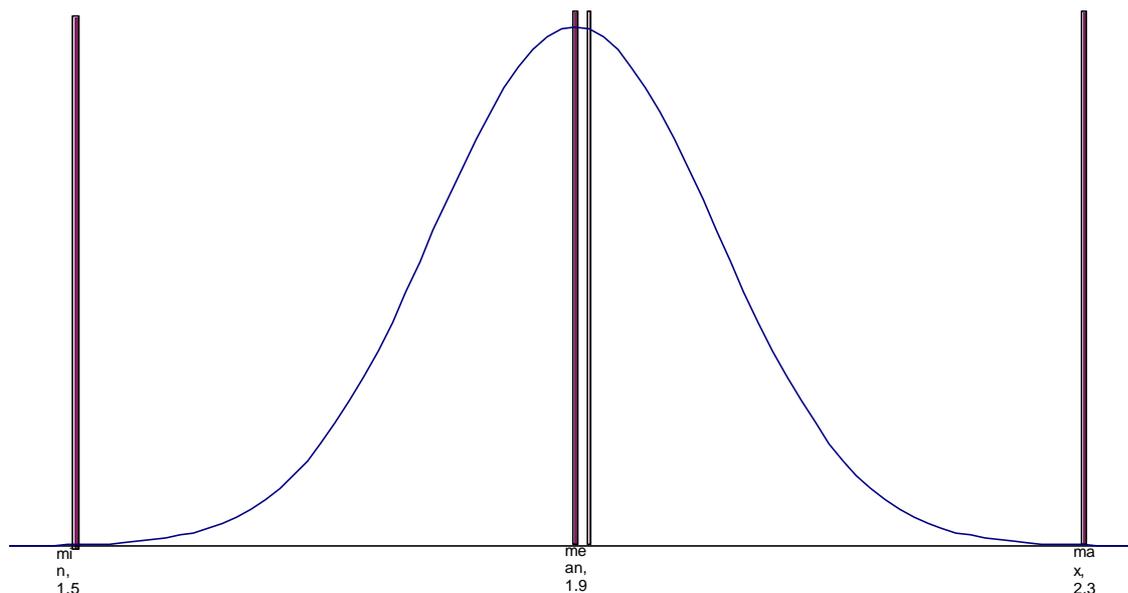
This is generally because the importance of the relationship is not always understood or is considered to be too complex; this foreword is intended to demonstrate that the significance of the relationship and thus encourage Codex Commodity Committees to address the sampling requirements in their Standards.

#### Specification Limit and Interpretation of Results

It is important that a Codex Commodity Committee considers and then defines exactly how the specification is to be interpreted. Without this information it is difficult to develop the methods of sampling and analysis which are then to be used to interpret the specification. This may be best illustrated by the example below:

Let us assume that a lot of 1 000 units of, say, a foodstuff is to be investigated to ascertain whether it is in compliance with a Codex specification of 2 mg/kg lead.

If each of the 1 000 units were to be sampled and analysed for its lead content, then the distribution of lead in the individual units may be shown diagrammatically below:



**Figure:** plot of the distribution of lead in the 1 000 units, with minimum concentration of 1.5 mg/kg, mean concentration in the lot of 1.9 mg/kg and maximum concentration of 2.3 mg/kg. The specification limit is 2 mg/kg.

Two countries may have different national rules for the interpretation of results from lots.

Country A requires: that each and every item in the lot meets the specification. In this example it means that all 1 000 units, if analysed separately, would have to be less than 2.0 mg/kg. Here a significant number of units are greater than 2.0 mg/kg so the lot would be deemed to be in non-compliance with the Codex specification and so would be rejected, but

Country B requires: that the mean value of the characteristic in the lot is to be less than the Codex specification. In this case the mean value is 1.9 mg/kg so the lot would be deemed to be in compliance with the Codex specification.

Consequence: the two countries A and B will make different judgements as to compliance with a Codex specification on essentially the same lot. This is unacceptable and can only be avoided if the sampling procedures are elaborated at the same time as the commodity standard is elaborated in the Commodity Committee. In addition it should also be noted that the number of units to be analysed also influences the decision on compliance (see below).

The approach to be taken must be defined before any sampling procedure is discussed. At present there is no information given as to the basis on which the Codex specification is to be evaluated prior to discussions on sampling commencing. This creates severe difficulties when methods of sampling are developed. The procedure for the analysis of the individual sample units is now well defined within Codex, but the framework within which the results are to be used is not.

### **Relationship Between Value of a Characteristic in a Commodity Standard and Methods of Analysis and Sampling Used for its Estimation**

Before any characteristic in any Codex Standard is elaborated it must be appreciated that the value of the characteristic in that Codex Standard is dependent on the procedures used to estimate that value. In particular, the estimate of the value may be dependent upon the method of analysis used, but is always dependent on the method of sampling used to verify compliance with the Standard. It is important for

delegates at Codex Commodity Committees to appreciate the influence that methods of analysis and sampling may have on the judgements that may be made with regard to the compliance of a lot with respect to a Codex Commodity Standard. Without common and uniform methods of analysis and sampling procedures different authorities will make different judgements as to whether any particular lot is in compliance with its Codex specification, as has been illustrated above. The relationship between the value of a characteristic in a Codex Commodity Standard and the method of analysis to estimate that value can be readily appreciated, but the link between the value of the characteristic and the method of sampling is less well understood.

This is best illustrated by example, taking first methods of analysis, and then methods of sampling.

#### Methods of Analysis

This may be best illustrated by reference to the “types” of methods of analysis which have been adopted by the Codex Alimentarius Commission. The CAC has stated that as Type I methods “define” the value of the characteristics in the Standard only a single Type I method can be prescribed. Methods of analysis for “fat” are Type I methods. It is possible to determine the “fat” content in a sample by two equally validated methods of analysis, each conforming to a different analytical principle. As a consequence the application of these two methods to the same sample will result in two different, but equally valid, results. In order to remove this possibility the Codex system only allows the adoption of a single Type I method.

In addition it is a mandatory requirement to accept the Type I Codex method if the Standard itself is to be accepted - i.e. the separation of the value of the characteristic and the relevant Type I method is, in effect, meaningless. It has, therefore, been agreed by the Codex Committees on Methods of Analysis and Sampling and on General Principles that non-acceptance of the Codex defining methods, or acceptance of Codex Standards with substantial deviations in the Codex defining method, should be taken to mean acceptance of the Codex Standard with a specified deviation.

Codex Type II and III methods determine the content of a defined chemical entity and these methods may be used interchangeably depending upon the particular situation except that Type II Codex methods are intended to be obligatory in cases of disputes concerning the results of analysis. However this approach may be modified as a result of the present discussions on the introduction of a criteria (performance-based) approach to methods of analysis in Codex Commodity Standards.

#### Methods of Sampling

The same considerations as apply to methods of analysis also apply to methods of sampling. This may also be best illustrated by a simple example.

One of the criteria by which the quality of a lot may be judged is the acceptable quality level (AQL) for a specification in a lot. In simple terms, the acceptable quality level in a lot is the percentage of defective items that is considered acceptable as a process average and is accepted with a given high probability of acceptance (usually in the region of 95%). For a specification in a batch two countries may have different acceptable quality levels i.e.

Country A may prescribe an acceptable quality level of 0.1%, i.e. it requires with a high (95 %) level of confidence that 99.9% of the product meets the specification whereas

Country B has prescribed an AQL of 10%, i.e. that country requires with a high (95 %) level of confidence that 90% of the product meets the specification.

The amount of sampling and the commodity specification required to determine the compliance of these two batches is different in each case and thus there is no harmonisation of sampling. If left undefined these two countries could make different judgements as to whether a particular lot would comply with a Codex specification.

One of the critical aspects of sampling is that the numbers of units must be taken at random from the batch. This is often difficult to achieve and the approach to randomisation will produce different decisions as to compliance or non-compliance of a batch. It is therefore important that if a uniform approach to sampling is

to be taken, that procedures for randomisation are carefully defined.

This, and similar, procedures must be defined **before** sampling plans are discussed.

### Timing of the Development of Sampling and Analysis Procedures

It has been illustrated above that the type of sampling criteria and the lot acceptance procedure used affects whether a lot may be deemed to be in compliance with its specification. It is therefore necessary that when characteristics within a Standard are elaborated, the sampling and lot acceptance procedures to be prescribed to verify those characteristics are also considered at the same time, so that the characteristics are related to the procedures.

It is important to recognise that without general instructions being given to those preparing Codex sampling plans, non-equivalent interpretation of Codex Commodity Standards will occur, thus giving the potential for trade disputes.

**To define a numeric value in a Standard is not enough: its interpretation also needs to be defined!**

**1.1** Insert the 3<sup>rd</sup> § : "No sampling plan can ensure that every items of a lot are conforms. These sampling plans are nevertheless useful to guarantee an acceptable quality level."

### **Insert a new section 1.3 Users of sampling plans recommended by the Guidelines**

The sampling plans described in these Guidelines may be implemented either by Governmental food control authorities, either by professionals themselves (self inspection). In the latter case, these Guidelines enable the Governmental authorities to check the relevance of the sampling plans implemented by the professionals."

#### **Table 1**

The heading of the Table should be amended as indicated below. This is a change in the presentation but the content of the Table is unchanged

In the last column, under "Other Sampling Situations" the indent "Punctual Sampling" should read "Pragmatic Sampling"

	Sampling of individualisable bulk material <sup>1</sup>		Single sampling of individual <sup>2</sup> items for statistical inspection at reception		
	Homogeneous goods	Homogeneous goods  for statistical inspection on reception by variables of percent nonconforming	By attributes of percent nonconforming (refer to 2.4.2 for the particular case of zero acceptance number)	by variables of percent nonconforming	of an average content <sup>3</sup>  Example: sodium content of a dietary food

#### **2.2.1 Lot**

**Note:** A **continuous series of lots** is a series of lots produced, manufactured or commercialised on a continuous manner, under conditions presumed uniforms."

<sup>1</sup> Single sampling in the case of homogeneous material

<sup>2</sup> or individualisable

<sup>3</sup> 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.

Insert a new

### 2.2.2 Consignment

A consignment is either a portion of a lot, either a set of several lots.

But in the case of statistical inspection, the consignment shall be considered as a new lot for the interpretation of the results."

And renumber accordingly the following clauses

Rewrite 2.2.5 (or new 2.2.6)

### "2.2.6 Item or increment

- a) Item : Actual or conventional object which may be designated as a unit of a lot, and which is drawn to form a sample.
- b) Increment : Quantity of material drawn at one time from a larger quantity of material to form a sample."

### 2.2.6 (or 2.2.7 Sampling plan)

Add the following after the 1<sup>st</sup> para.

More precisely, a sampling plan is a scheme defining the number of items and non-conforming items required in a sample to evaluate the compliance status of a lot."

### Complete 2.2.8 (or 2.2.9) Homogeneity

A lot is **homogenous** *relative to a given characteristic* if the characteristic is uniformly distributed (according to a given probability law) throughout the lot<sup>4</sup>.

NOTE: A lot being homogeneous for a given characteristic does not mean that the value of the characteristic is the same throughout the lot.

The end is unchanged

Insert 2 new sections :

### 2.2.11 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.

### 2.2.12 Producers' risk and consumers' risk

#### Producers' risk (PR)

On the OC curve (see 2.2.11) of a sampling plan, the producers' risk corresponds to the probability to reject a lot having a proportion  $P_1$  of defective items (generally low), fixed by the sampling plan. According to the producer, such a lot should not be rejected.

In other words, it is the probability to wrongly reject a lot.

Generally, the PR is expressed by a proportion noted  $P_{95}$  corresponding to the proportion of defective items in the lot accepted in 95 % of cases (i.e. rejected in 5 of cases).

#### Consumers' risk (CR)

On the OC curve (see 2.2.11) of a sampling plan, the consumers' risk corresponds to the probability to accept

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<sup>4</sup> After checking by a statistical test for comparison of 2 samples, i.e. parametric or non parametric tests of the characteristic (e.g. Chi-2 test or Kolmogorof-Smirnof test).

a lot having a proportion  $P_2$  of defective items (generally low), fixed by the sampling plan.

According to the consumer, such a lot should be rejected.

In other words, it is the probability to wrongly accept a lot.

Generally, the CR is expressed by a proportion noted  $P_{10}$  corresponding to the proportion of defective items in the lot accepted in 10 % of cases (i.e. rejected in 90 % of cases).

### Discrimination Distance (D)

The discrimination distance (D) is the absolute distance between the producers' risk (PR) and the consumers' risk (CR), and should be specified, taking into account the values of the population standard deviations of sampling and of measurements."

Delete 2.2.15 (in fact placed before)

### 2.3.3, 5<sup>th</sup> para.

Replace the 1<sup>st</sup> sentence as follows : "**If the lot is heterogeneous** and so a random sample may not be representative of the lot, stratified sampling may be a solution."

### 2.3.7 ( becomes 2.4) Estimation errors

1<sup>st</sup> para. unchanged. Second para. should read as follows:

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 desirable that the sampling errors associated with any sampling plan, as well as the measurement errors associated with the analysis should be quantified and minimised.

When the controlled characteristics need to be analysed, any decision on a lot from a sample shall take into account the measurement error, in comparison with the sampling error (question to be addressed in a separate Codex document)."

2.4 (and following) becomes 2.5 (and so on)

### 2.4.1.2.2 (new : 2.5.1.2.2)

#### Table 3

Last row, last cell should read:  $\bar{x} < L + K\sigma$ , or  $\bar{x} > U - K\sigma$  (instead of :  $U-L < 2 K\sigma$ )

In the EXAMPLE, the following changes should be made

Results of measurements :

- $x_5 = 111$  mg (instead of 125 mg);
- $\bar{x} = \frac{x_1 + x_2 + x_3 + x_4 + x_5}{5} = 118$  mg (instead of 120.8 mg)
- $\sigma$  denotes the known standard deviation :

$\sigma = 3,5$  mg, according to experimental data on an extended period of production, made available to the inspectors by the professionals.

- Conclusion : knowing that  $U - K\sigma = 120 - (1,39 \times 3,5) = 115,1$  mg, then  $\bar{x} > U - K\sigma$  and the lot is rejected.

### 2.4.1.2.3 (new : 2.5.1.2.3) - Table 4

Last row, last cell should read:  $\bar{x} < L + Ks$ , or  $\bar{x} > U - Ks$  (instead of :  $U-L < 2 K\sigma$ )

The EXAMPLE shall read :

Results of measurements<sup>5</sup> :

- $x_5$  denotes the sodium content measured in the fifth item, = 111 mg ;
- $\bar{x}$  denotes the mean of the sodium contents obtained on the sample of five items  

$$\bar{x} = \frac{x_1 + x_2 + x_3 + x_4 + x_5}{5} = 118 \text{ mg}$$
- $s$  denotes the standard deviation estimator calculated on the sample :

$$s = \sqrt{\sum_{i=1}^{i=n} \frac{(x_i - \bar{x})^2}{n-1}} = 4,6 \text{ mg}$$

- Conclusion : knowing that  $U - Ks = 120 - (1,24 \times 4,6) = 114,3 \text{ mg}$ , then  $\bar{x} > U - Ks$  and the lot is rejected (see Table 3)"

3.1 : Add a preliminary note at the beginning :

**"Preliminary note<sup>6</sup>** : Given the requirements due to probabilities linked to sampling by attributes, the plans of this section enable a rational choice between the existing plans referring to AQL, as defined in Section 4.2. In order to ensure their compatibility, similar rules for acceptance/rejection, as well as categories of lot size have been chosen for this section and for section 4.2."

3.2.2 Change from the 2<sup>nd</sup> § of p. 28 as follows :

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 :

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

where :

$P_a$  is the probability of acceptance of a lot containing :

- a given percentage of defective items ( $P_d$ ) (a defective item having a concentration in micro-organisms greater than M), i.e. lots for whose the concentration in micro-organisms is greater than M), and
- a given percentage of marginally acceptable items ( $P_m$ ) (a marginally acceptable item having a concentration in micro-organisms between  $m$  and  $M$ ) ;

$n$  is the number of items in the sample

$c$  is the maximum number allowed of marginal items.

Summary of three-class attributes sampling plans (following : unchanged)

### 4.1 Figure 5

Last line, p. 32 : change as follows "The graph shows that, for a constant AQL, the higher the sample size,

<sup>5</sup> In order to highlight the difference with the  $\sigma$  method, the numerical values are identical to those indicated in the case of the  $\sigma$  method.

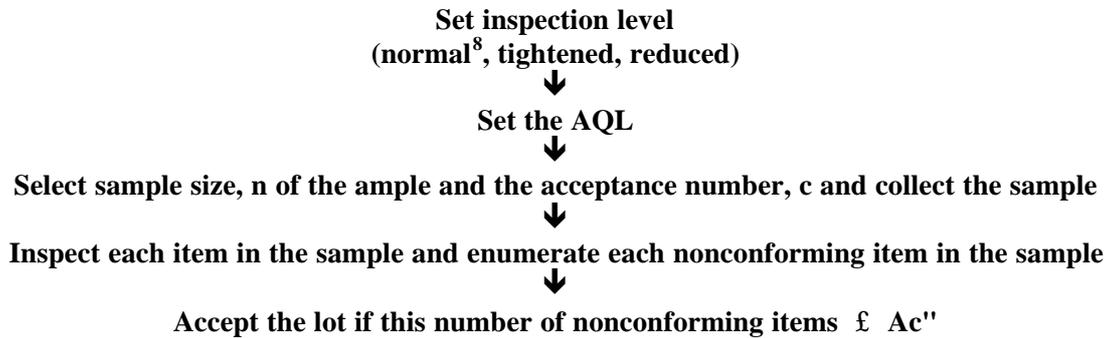
<sup>6</sup> According to 7.1 of Standard ISO 2859-2.

the smaller the risk to the consumer<sup>7</sup> of accepting lots with high defective rates."

**4.2.1 General** should read as follows :

The principle of such sampling plans is presented in Section 2.5.1.1.

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



**In 4.2.2.4 Discontinuation of Inspection** should read as follows

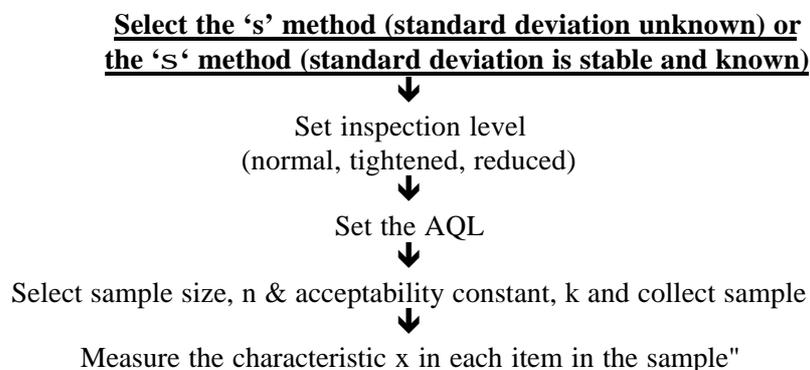
Once tightened inspection has been introduced, the acceptance procedures of ISO 2859 should be discontinued if five, or more, lots are not accepted and all products from that source must be rejected. Importation and inspection should not resume until the responsible authority is satisfied that the producer 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."

**4.3.1 General** should read as follows:

The principle of such sampling plans is presented in Section 2.5.1.2.

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



<sup>7</sup> The consumer risk generally corresponds to the LQ, defective rate in the lots accepted in 10 % of the cases.

<sup>8</sup> Any inspection level other than the normal control shall be justified by the users of sampling plans.

## 4.3.2.2 Table 13 shall be :

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code D, AQL = 0,65%, n= 5, K =1,65  P <sub>95</sub> <sup>9</sup> = 0,28% P <sub>50</sub> <sup>10</sup> = 6,34% P <sub>10</sub> <sup>11</sup> = 25,9%	Probability to accept these lots : Normal inspection plan Letter-code E, AQL = 0,65%, n= 7, K =1,75  P <sub>95</sub> = 0,32% P <sub>50</sub> = 4,83% P <sub>10</sub> = 18,6%	Probability to accept these lots : Normal inspection plan Letter-code F, AQL = 0,65%, n= 10, K =1,84  P <sub>95</sub> = 0,36% P <sub>50</sub> = 3,77% P <sub>10</sub> = 13,2%	Probability to accept these lots : Normal inspection plan Letter-code G, AQL = 0,65%, n= 15, K =1,91  P <sub>95</sub> = 0,45% P <sub>50</sub> = 3,09% P <sub>10</sub> = 9,4%
0%	100%	100%	100%	100%
1%	96%	96%	97,5%	98%
2%	94%	94%	92,5%	95%
3%	86%	86%	86%	86%
4%	82%	82%	80%	78%
5%	78%	76%	73%	70%
6%	74%	70%	66%	62%
7%	69%	66%	59%	54%
8%	66%	60%	54%	46%
9%	61%	56%	48%	39%
10%	58%	52%	42%	34%
15%	42%	34%	23%	14%
20%	30%	21%	12%	5%
25%	23%	13%	6%	1,5%
30%	15%	8%	2%	0%
35%	10%	5%	1%	0%
40%	6%	2%	0%	0%
45%	4%	1%	0%	0%
50%	2%	0%	0%	0%
100%	0%	0%	0%	0%

TABLE 13

<sup>9</sup> P<sub>95</sub> = Rate of non-conforming items in lots accepted in 95% of cases<sup>10</sup> P<sub>50</sub> = Rate of non-conforming items in lots accepted in 50% of cases<sup>11</sup> P<sub>10</sub> = Rate of non-conforming items in lots accepted in 10% of cases

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code H, AQL = 0,65%, n= 20, K =1,96  P <sub>95</sub> = 0,49% P <sub>50</sub> = 2,69% P <sub>10</sub> = 7,48%	Probability to accept these lots : Normal inspection plan Letter-code I, AQL = 0,65%, n= 25, K =1,98  P <sub>95</sub> = 0,56% P <sub>50</sub> = 2,53% P <sub>10</sub> = 6,5%	Probability to accept these lots : Normal inspection plan Letter-code J, AQL = 0,65%, n= 35, K =2,03  P <sub>95</sub> = 0,60% P <sub>50</sub> = 2,21% P <sub>10</sub> = 5,1%	Probability to accept these lots : Normal inspection plan Letter-code K, AQL = 0,65%, n= 50, K =2,08  P <sub>95</sub> = 0,64% P <sub>50</sub> = 1,94% P <sub>10</sub> = 4,5%
0%	100%	100%	100%	100%
1%	84%	84%	84%	84%
2%	63%	62%	56%	48%
3%	44%	40%	32%	22%
4%	32%	28%	19%	10%
5%	24%	18%		4%
6%	16%	12%	6%	
7%	12%	8%	3,5%	1%
8%	8%	6%	2%	0,5%
9%	6%	4%	1%	
10%	4%	2%	0%	0%
15%	0%	0%	0%	0%

FOLL. TABLE 13

**4.3.2.3 Table 14**

1) The titles in the cells should be as follows

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code D, NQA = 2,5%, n= 5, K =1,24  P <sub>95</sub> = 1,38% P <sub>50</sub> = 12,47% P <sub>10</sub> = 35%	Probability to accept these lots : Normal inspection plan Letter-code E, NQA = 2,5%, N= 7, K =1,33  P <sub>95</sub> = 1,5% P <sub>50</sub> = 10,28% P <sub>10</sub> = 27,4%	Probability to accept these lots : Normal inspection plan Letter-code F, NQA = 2,5%, n= 10, K =1,41  P <sub>95</sub> = 1,61% P <sub>50</sub> = 8,62% P <sub>10</sub> = 21,4%	Probability to accept these lots : Normal inspection plan Letter-code G, NQA = 2,5%, n= 15, K =1,47  P <sub>95</sub> = 1,91% P <sub>50</sub> = 7,5% P <sub>10</sub> = 16,8%
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2) Only the entries for the following percentages should be retained:

0,1, 2 ,3 ,4 ,5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 40, 45, 50, 60. All the others should be deleted

**Second part of Table 14 (p.45)**

1) The titles in the cells should be as follows

Defective rates in the lots	Probability to accept these lots : Normal inspection plan Letter-code H, AQL = 2,5%, N= 20, K =1,51  P <sub>95</sub> = 2,07% P <sub>50</sub> = 6,85% P <sub>10</sub> = 14,2%	Probability to accept these lots : Normal inspection plan Letter-code I, AQL = 2,5%, n= 25, K =1,53  P <sub>95</sub> = 2,23% P <sub>50</sub> = 6,54% P <sub>10</sub> = 12,8%	Probability to accept these lots : Normal inspection plan Letter-code J, AQL = 2,5%, n= 35, K =1,57  P <sub>95</sub> = 2,38% P <sub>50</sub> = 6% P <sub>10</sub> = 10,9%	Probability to accept these lots : Normal inspection plan Letter-code K, AQL = 2,5%, n= 50, K =1,61  P <sub>95</sub> = 2,51% P <sub>50</sub> = 5,48% P <sub>10</sub> = 8,7%
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2) Only the entries for the following percentages should be retained:

0,1, 2 ,3 ,4 ,5, 6, 7, 8, 9, 10, 12, 13 , 14, 15, 20, 25. All the others should be deleted.

**4.3.3.2 – “Table 16” should read “Table 17” (p.48)**

The entries for 9.6, 12.3, should be deleted

The following entry should be added :

0,65%	91,5%	91,4%	91,2%	92,1%
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All other entries are unchanged

**SECTION 5**

Under the title, modify the reference as follows :

" (see ISO/DIS 10725-2.3 and ISO 11 648-1)"

**5.2 Standardised sampling procedures for the inspection of individual lots** should read :

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, in particular for inspection of bulk material :

- the establishment of *standard deviations, costs, producer’s risk quality, consumer’s risk quality and discrimination distance (see definitions in 2.2.12)*

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

- 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:

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

where  $m_A$  is the producers' risk  
 $D$  is the discrimination distance.

- **Drawing of increments from the lot**

An appropriate sampling device should be used together with representative sampling to afford  $n_i$  increments ( $i$  is the increment of rank  $i$ )

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

The  $n$  increments are pooled in order to produce  $n_c$  composite samples (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  $n_c \cdot n_t \cdot n_m$  measurements per lot

- **Determination of lot acceptability**

The sample grand average ( $\bar{x}$ ) is calculated from 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  $\bar{x} > \bar{x}_U$

◦ 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  $\bar{x} > \bar{x}_U$