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Milk and milk products — Sampling — Inspection by attributes

Lait et produits laitiers — Échantillonnage — Contrôle par attributs

Reference number
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Foreword

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Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5538 was prepared by Technical Committee ISO/TC 34, *Agricultural food products,* in collaboration with the International Dairy Federation (IDF) and the Association of Official Analytical Chemists (AOAC) and will also be published by these organizations.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Milk and milk products — Sampling — Inspection by attributes

0 Introduction

The sampling theory used in this International Standard is based on classifying a unit as "good" or "defective". A "good" unit is one which meets the requirements of a specification, while a "defective" unit is one which does not. It is essential that the sample is taken at random. If it is not, the sampling plans will not give the stated protection. See annex A.

1 Scope and field of application

1.1 This International Standard specifies sampling plans for the inspection by attributes of milk and milk products. It is intended to be used to choose a sample size for any situation where it is required to measure the conformity to a specification of a lot of a dairy product by examination of a representative sample. Methods of sampling for milk and milk products are given in ISO 707.

1.2 This International Standard is applicable to the sampling of all milk products submitted in discrete lots, irrespective of whether the lots are from the same production. The acceptance or otherwise of any lot is a matter for the parties to a contract and is outside the scope of this International Standard.

1.3 This International Standard is intended to be used in all cases where attribute sampling plans are required for a dairy product, except that if specific compositional standards, specifications or contracts include different sampling schemes, those schemes are to be used.

1.4 This International Standard is not applicable to sampling for microbiological defects, unless otherwise agreed by the interested parties.

2 References

ISO 707, *Milk and milk products — Methods of sampling.*

ISO 2859 : 1974, *Sampling procedures and tables for inspection by attributes.* [1]

ISO 2859 : 1974/Addendum 1 : 1977, *General information on sampling inspection, and guide to the use of the ISO 2859 tables.* [1]

ISO 3534, *Statistics — Vocabulary and symbols.*

3 Definitions

For the purpose of this International Standard, the definitions given in ISO 3534 apply.

4 ISO 2859 sampling plans

ISO 2859 describes plans for use in all situations, and gives an account of the theoretical background to the sampling tables. The plans are indexed by batch or lot size and acceptable quality level (AQL). AQL is defined in ISO 2859 and in its Addendum 1; it can be considered to be the average level of quality which if maintained by a producer would result in the acceptance of most of his production.

5 Selection of sampling plan

5.1 Classification of defects

Before selection of a sampling plan, the contract or specification shall clearly define all critical, major and minor defects in such a way that they are unambiguously understood by all users of the contract, specification or document containing or referring to the sampling plan.

5.1.1 A **critical defect** is one that would make the product unacceptable. For the purpose of this International Standard, critical defects relate to the presence of toxic contaminants at a critically high level. Examples include heavy metals and pesticide residues.

In this case, the method to be adopted shall be that described in annex B[2]. It is necessary to decide on an acceptable risk of not detecting a certain percentage of defectives, where a defective is a unit which contains more than the critical level of the contaminant. It is impossible to guarantee freedom from contamination.

5.1.2 A **major defect** is one that is likely to make the product unfit for use, i.e., in the case of milk and milk products, unfit for sale to the consumer. A major defect would result in the

1) The edition of ISO 2859 relevant to this International Standard is currently under revision. Any necessary alterations, for example in terminology, as a consequence of this revision will be carried out to this International Standard when it is next revised.

2) Annex B is an extract of clause 9 of ISO 2859/Addendum 1.

product spoiling or becoming unfit for sale or processing. Examples include

a) composition defect, where this would affect keeping quality;

b) contamination with inhibitory substances;

c) integrity of packaging;

d) visible contamination with dirt.

Sampling plans for major defects shall be selected from the tables using an AQL of not more than 6,5 %.

5.1.3 A **minor defect** is a failure to comply with a specification, but which does not make the unit unfit for use and sale, nor cause it to spoil. Examples include

a) a unit, the chemical composition or net content of which falls outside, but close to, a specification limit;

b) small abnormalities in appearance.

Sampling plans for minor defects shall be selected from the tables using an AQL of not more than 10 %.

5.2 Choice of inspection level and AQL

5.2.1 The sampling plan shall be selected from the tables, using the lot size and the agreed AQL.

In these tables, n is the sample size, Ac is the acceptance number, and Re is the rejection number.

Example :

For a sample size of $n = 13$, Ac = 0 and Re = 1, this means that if a sample of 13 units contains no defectives, the lot shall be accepted; if the sample contains 1 defective, the lot shall be rejected.

Tables 1 to 5 are derived from ISO 2859 and refer to Inspection Levels I, S-4, S-3, S-2 and S-1. Inspection Level I is preferred.

Using any of the S plans will result in increased risks, and they shall not be used without first checking that the associated risk is acceptable. Details of these risks are given in 5.2.2.

5.2.2 Inspection Levels S-4, S-3, S-2 and S-1 may be used where relatively small sample sizes are necessary and large sample risks can or must be tolerated. As a consequence of using these special levels, there is an increased probability of making a wrong decision. Firstly, the consumer's risk increases. This is illustrated in tables 6 to 9. Table 6 refers to plans with an AQL of 2,5 %, table 7 to an AQL of 4,0 %, table 8 to an AQL of 6,5 % and table 9 to an AQL of 10 %.

Each table contains :

— the sample size (n) and the appropriate lot size at the separate inspection levels;

— maximum number of defective units permitted in the sample — acceptance number (Ac);

— minimum number of defective units required in the sample to reject the lot — rejection number (Re);

— limiting quality — LQ.

If the sample size is small, LQ is high; if the sample size increases, LQ is reduced at the same AQL.

For example, in table 6, the inspection plan in which the sample size is 5 and LQ = 45 % appears in all the inspection levels but only at S-1 level can all lot sizes be inspected.

At the S-4 and I Inspection Levels the sample size of 5 can only be taken when the lot size does not exceed 150.

The fact that the consumer's risk (and at the same time the LQ) becomes smaller as the size of the inspected lot becomes greater, is justified on economic grounds.

Inspection plans in which the LQ is several times greater than the AQL are unsuitable for both consumer and producer. If a lot of 35 000 units is considered, Inspection Level I would require a sample size of 125, giving an LQ of 11 % (i.e. 95 % of lots containing 11 % of defects would be rejected). S-1 would require a sample size of 5, giving an LQ of 45 %. An LQ of 45 % is so much greater than the AQL of 2,5 % that the concept of AQL has become meaningless. Furthermore, the sample of 5 would wrongly reject more than 10 % of lots containing 2,5 % of defects.

Increasing the sample size increases both the protection to the consumer, and the discrimination of the sampling plan; this increased discrimination is one of the major reasons for relating sample size to lot size. Users of this International Standard will find full operating characteristics for each plan in ISO 2859; these relate the probability of acceptance to per cent defective in the lot.

6 Records

Successful operation of this type of sampling plan requires the maintenance of comprehensive records of the results of inspection, and the plan in use. Interchange of information between both parties would be useful, and it is recommended that each party make such information available to the other as required.

7 Selection of units

The sampling theory used for the plans in ISO 2859 and thus in this International Standard assumes that sampling is at random, which means that each unit in the lot should have the same probability of appearing in the sample. Every effort shall be made to obtain a random sample. Whenever possible a formal randomization procedure, as described in ISO 2859/Addendum 1, clause 15, should be used (see annex C). If this is not done, the risks associated with the plans cannot be assumed to be those expected. Formal randomization is not difficult, although it can be tedious and time-consuming.

Table 1.1 — Inspection Level I — AQL = 2,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 150	5	0	1	8	0	1	2	0	1
151 to 500	20	1	2	32	1	2	8	0	2
501 to 1 200	32	2	3	32	1	2	13	1	3
1 201 to 3 200	50	3	4	50	2	3	20	1	4
3 201 to 10 000	80	5	6	80	3	4	32	2	5
10 001 to 35 000	125	7	8	125	5	6	50	3	6
35 001 to 150 000	200	10	11	200	8	9	80	5	8
150 001 to 500 000	315	14	15	315	12	13	125	7	10
Over 500 000	500	21	22	500	18	19	200	10	13

Table 1.2 — Inspection Level I — AQL = 4,0 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 90	3	0	1	5	0	1	2	0	1
91 to 280	13	1	2	20	1	2	5	0	2
281 to 500	20	2	3	20	1	2	8	1	3
501 to 1 200	32	3	4	32	2	3	13	1	4
1 201 to 3 200	50	5	6	50	3	4	20	2	5
3 201 to 10 000	80	7	8	80	5	6	32	3	6
10 001 to 35 000	125	10	11	125	8	9	50	5	8
35 001 to 150 000	200	14	15	200	12	13	80	7	10
Over 150 000	315	21	22	315	18	19	125	10	13

Table 1.3 — Inspection Level I — AQL = 6,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 25	2	0	1	3	0	1	2	0	1
26 to 150	8	1	2	13	1	2	3	0	2
151 to 280	13	2	3	13	1	2	5	1	3
281 to 500	20	3	4	20	2	3	8	1	4
501 to 1 200	32	5	6	32	3	4	13	2	5
1 201 to 3 200	50	7	8	50	5	6	20	3	6
3 201 to 10 000	80	10	11	80	8	9	32	5	8
10 001 to 35 000	125	14	15	125	12	13	50	7	10
Over 35 000	200	21	22	200	18	19	80	10	13

Table 1.4 — Inspection Level I — AQL = 10 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 90	5	1	2	8	1	2	2	0	2
91 to 150	8	2	3	8	1	2	3	1	3
151 to 280	13	3	4	13	2	3	5	1	4
281 to 500	20	5	6	20	3	4	8	2	5
501 to 1 200	32	7	8	32	5	6	13	3	6
1 201 to 3 200	50	10	11	50	8	9	20	5	8
3 201 to 10 000	80	14	15	80	12	13	32	7	10
Over 10 000	125	21	22	125	18	19	50	10	13

Table 2.1 — Inspection Level S-4 — AQL = 2,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 150	5	0	1	8	0	1	2	0	1
151 to 1 200	20	1	2	32	1	2	8	0	2
1 201 to 10 000	32	2	3	32	1	2	13	1	3
10 001 to 35 000	50	3	4	50	2	3	20	1	4
35 001 to 500 000	80	5	6	80	3	4	32	2	5
Over 500 000	125	7	8	125	5	6	50	3	6

Table 2.2 — Inspection Level S-4 — AQL = 4,0 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 90	3	0	1	5	0	1	2	0	1
91 to 500	13	1	2	20	1	2	5	0	2
501 to 1 200	20	2	3	20	1	2	8	1	3
1 201 to 10 000	32	3	4	32	2	3	13	1	4
10 001 to 35 000	50	5	6	50	3	4	20	2	5
35 001 to 500 000	80	7	8	80	5	6	32	3	6
Over 500 000	125	10	11	125	8	9	50	5	8

Table 2.3 — Inspection Level S-4 — AQL = 6,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 25	2	0	1	3	0	1	2	0	1
26 to 150	8	1	2	13	1	2	3	0	2
151 to 500	13	2	3	13	1	2	5	1	3
501 to 1 200	20	3	4	20	2	3	8	1	4
1 201 to 10 000	32	5	6	32	3	4	13	2	5
10 001 to 35 000	50	7	8	50	5	6	20	3	6
35 001 to 500 000	80	10	11	80	8	9	32	5	8
Over 500 000	125	14	15	125	12	13	50	7	10

Table 2.4 — Inspection Level S-4 — AQL = 10 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 90	5	1	2	8	1	2	2	0	2
91 to 150	8	2	3	8	1	2	3	1	3
151 to 500	13	3	4	13	2	3	5	1	4
501 to 1 200	20	5	6	20	3	4	8	2	5
1 201 to 10 000	32	7	8	32	5	6	13	3	6
10 001 to 35 000	50	10	11	50	8	9	20	5	8
35 001 to 500 000	80	14	15	80	12	13	32	7	10
Over 500 000	125	21	22	125	18	19	50	10	13

Table 3.1 — Inspection Level S-3 — AQL = 2,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 500	5	0	1	8	0	1	2	0	1
501 to 35 000	20	1	2	32	1	2	8	0	2
35 001 to 500 000	32	2	3	32	1	2	13	1	3
Over 500 000	50	3	4	50	2	3	20	1	4

Table 3.2 — Inspection Level S-3 — AQL = 4,0 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 150	3	0	1	5	0	1	2	0	1
151 to 3 200	13	1	2	20	1	2	5	0	2
3 201 to 35 000	20	2	3	20	1	2	8	1	3
35 001 to 500 000	32	3	4	32	2	3	13	1	4
Over 500 000	50	5	6	50	3	4	20	2	5

Table 3.3 — Inspection Level S-3 — AQL = 6,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 50	2	0	1	3	0	1	2	0	1
51 to 500	8	1	2	13	1	2	3	0	2
501 to 3 200	13	2	3	13	1	2	5	1	3
3 201 to 35 000	20	3	4	20	2	3	8	1	4
35 001 to 500 000	32	5	6	32	3	4	13	2	5
Over 500 000	50	7	8	50	5	6	20	3	6

Table 3.4 — Inspection Level S-3 — AQL = 10 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 150	5	1	2	8	1	2	2	0	2
151 to 500	8	2	3	8	1	2	3	1	3
501 to 3 200	13	3	4	13	2	3	5	1	4
3 201 to 35 000	20	5	6	20	3	4	8	2	5
35 001 to 500 000	32	7	8	32	5	6	13	3	6
Over 500 000	50	10	11	50	8	9	20	5	8

Table 4.1 — Inspection Level S-2 — AQL = 2,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 35 000	5	0	1	8	0	1	2	0	1
Over 35 000	20	1	2	32	1	2	8	0	2

Table 4.2 — Inspection Level S-2 — AQL = 4,0 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 1 200	3	0	1	5	0	1	2	0	1
Over 1 200	13	1	2	20	1	2	5	0	2

Table 4.3 — Inspection Level S-2 — AQL = 6,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 150	2	0	1	3	0	1	2	0	1
151 to 35 000	8	1	2	13	1	2	3	0	2
Over 35 000	13	2	3	13	1	2	5	1	3

Table 4.4 — Inspection Level S-2 — AQL = 10 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 1 200	5	1	2	8	1	2	2	0	2
1 201 to 35 000	8	2	3	8	1	2	3	1	3
Over 35 000	13	3	4	13	2	3	5	1	4

Table 5.1 — Inspection Level S-1 — AQL = 2,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
All lot sizes	5	0	1	8	0	1	2	0	1

Table 5.2 — Inspection Level S-1 — AQL = 4,0 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 35 000	3	0	1	5	0	1	2	0	1
Over 35 000	13	1	2	20	1	2	5	0	2

Table 5.3 — Inspection Level S-1 — AQL = 6,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 500	2	0	1	3	0	1	2	0	1
Over 500	8	1	2	13	1	2	3	0	2

Table 5.4 — Inspection Level S-1 — AQL = 10 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	n	Ac	Re	*n*	Ac	Re	*n*	Ac	Re
Up to 35 000	5	1	2	8	1	2	2	0	2
Over 35 000	8	2	3	8	1	2	3	1	3

NOTE (Tables 1 to 5) — When using reduced inspection, if the acceptance number is exceeded but the rejection number is not reached, the consignment should be accepted but inspection should revert to normal inspection.

Table 6 — Single sampling plans at AQL = 2,5 %

n	Ac	Re	LQ* (%)	Lot size (units) for inspection levels shown				
				S-1	S-2	S-3	S-4	I
5	0	1	45	All lot sizes	Up to 35 000	Up to 500	Up to 150	Up to 150
20	1	2	22		Over 35 000	501 to 35 000	151 to 1 200	151 to 500
32	2	3	18			35 001 to 500 000	1 201 to 10 000	501 to 1 200
50	3	4	15			Over 500 000	10 001 to 35 000	1 201 to 3 200
80	5	6	13				35 001 to 500 000	3 201 to 10 000
125	7	8	11				Over 500 000	10 001 to 35 000
200	10	11	8,5					35 001 to 150 000
315	14	15	7,0					150 001 to 500 000
500	21	22	6,1					Over 500 000

Table 7 — Single sampling plans at AQL = 4,0 %

n	Ac	Re	LQ* (%)	Lot size (units) for inspection levels shown				
				S-1	S-2	S-3	S-4	I
3	0	1	63	Up to 35 000	Up to 1 200	Up to 150	Up to 90	Up to 90
13	1	2	32	Over 35 000	Over 1 200	151 to 3 200	91 to 500	91 to 280
20	2	3	28			3 201 to 35 000	501 to 1 200	281 to 500
32	3	4	23			35 001 to 500 000	1 201 to 10 000	501 to 1 200
50	5	6	20			Over 500 000	10 001 to 35 000	1 201 to 3 200
80	7	8	16				35 000 to 500 000	3 201 to 10 000
125	10	11	14				Over 500 000	10 001 to 35 000
200	14	15	11					35 001 to 150 000
315	21	22	9,6					Over 150 000

Table 8 — Single sampling plans at AQL = 6,5 %

n	Ac	Re	LQ* (%)	Lot size (units) for inspection levels shown				
				S-1	S-2	S-3	S-4	I
2	0	1	78	Up to 500	Up to 150	Up to 50	Up to 25	Up to 25
8	1	2	47	Over 500	151 to 35 000	51 to 500	26 to 150	26 to 150
13	2	3	41		Over 35 000	501 to 3 200	151 to 500	151 to 280
20	4	5	34			3 201 to 35 000	501 to 1 200	281 to 500
32	5	6	30			35 001 to 500 000	1 201 to 10 000	501 to 1 200
50	7	8	25			Over 500 000	10 001 to 35 000	1 201 to 3 200
80	10	11	20				35 001 to 500 000	3 201 to 10 000
125	14	15	18				Over 500 000	10 001 to 35 000
200	21	22	15					Over 35 000

* Limiting quality (see 5.2.2).

Table 9 — Single sampling plans at AQL = 10 %

n	Ac	Re	LQ* (%)	Lot size (units) for inspection levels shown				
				S-1	S-2	S-3	S-4	I
5	1	2	66	Up to 35 000	Up to 1 200	Up to 150	Up to 90	Up to 90
8	2	3	60	Over 35 000	1 201 to 35 000	151 to 500	91 to 150	91 to 150
13	3	4	50		Over 35 000	501 to 3 200	151 to 500	151 to 280
20	5	6	46			3 201 to 35 000	501 to 1 200	281 to 500
32	7	8	37			35 001 to 500 000	1 201 to 10 000	501 to 1 200
50	10	11	32			Over 500 000	10 001 to 35 000	1 201 to 3 200
80	14	15	26				35 001 to 500 000	3 201 to 10 000
125	21	22	24				Over 500 000	Over 10 000

Annex A

Statistical theory

(This annex forms an integral part of the standard.)

A.1 The sampling plans included in ISO 2859, from which these plans are drawn, are based on either Poisson or binomial distribution theory.

Binomial distribution is used for the smaller sample sizes, and Poisson distribution for those schemes where this distribution is an adequate approximation to the binomial. Sub-clause 11.1 of ISO 2859 gives more details.

A.2 It is only necessary to satisfy two requirements in order to use the sampling theory. Firstly, an individual unit can only be "good" or "defective" as defined in the introduction. Secondly, the sample must be drawn at random as defined in ISO 2859, clause 7. It is not necessary to make any assumptions about the distribution of defectives within the lot.

* Limiting quality (see 5.2.2).

Annex B

Critical defects[1)]

(This annex forms an integral part of the standard.)

Critical defects form a special category. It is impossible to choose any value of per cent defective for these defects and say, "This percentage of defectives is tolerable".

The solution generally adopted, where non-destructive inspection is involved, is to lay down that critical features are to be inspected using a sample size equal to the lot size and an acceptance number of zero. This is 100 % inspection, but is should be noted that it is not the traditional 100 % sorting. Here there is no attempt to sort the articles into the good and the bad but an attempt to check that there are no bad ones. If a critical defective is found, this does not merely mean that it is put into a different box and the inspection continues; it means that the whole lot is rejected (although rejection does not necessarily mean scrapping — see clause 1 [of ISO 2859/Addendum 1]).

Whenever possible, it should also mean that production is stopped while a thorough investigation takes place to attempt to discover how the defect arose and to devise methods to prevent another occurrence. The reason for this procedure is to try to prevent the production of critical defectives and to avoid giving the manufacturer the impression that as the inspector will sort them out for him it will not matter too much if he produces some. Even the best inspector may occasionally fail to notice a defect, so it is only by preventing critical defectives from being made that it can be ensured that none will get through to the customer.

If it is ever thought that any particular critical defect does not warrant this procedure, then serious consideration should be given to having it reclassified as a major defect. Critical defects really must be critical; then no amount of effort is too great.

According to the definition of a critical defect in ISO 2859, this classification should be used for a defect that is likely to cause hazardous or unsafe conditions for individuals using, maintaining, or depending upon the product.

The wording "is likely to" is important. There is sometimes a tendency to replace these words by "could possibly" and hence to classify everything as critical, since it is always possible to make up a story in which some trivial happening at the beginning leads to catastrophe at the end.

If this approach is adopted, the main result is to devalue the critical classification, and the genuine criticals may not be treated as severely as they should be.

The critical classification is also available for a defect that *is likely* to prevent performance of the practical function of *a major* end item. Again the italicized words are important if the critical classification is not to be devalued.

Where the only possible inspection for critical defects is destructive, the search for ways of preventing them from ever being made at all is even more important. In this case, we cannot have a sample which is 100 % of the lot, and it is necessary to decide what sample should be taken for inspection for critical defects. This can be done using a simple formula connecting the per cent defective for which, if it were present, we would wish to be almost certain of finding at least one defective in the sample, the sample size and the risk we are prepared to take of failing to find a defective.

The formula is

$$\text{Sample size} = \frac{\text{a factor depending upon the risk}}{\text{\% defective it is wished to detect if present}}$$

The factor in the numerator of this formula depends upon the risk of failing to find a defective in the sample, as follows :

Risk	Factor[1)]
1 in 10	230,26
1 in 100	460,52
1 in 1 000	690,78
1 in 10 000	921,04
1 in 100 000	1 151,30
1 in 1 000 000	1 381,56

1) The factor of other values of the risk, if required, can be calculated as $230{,}26 \left| \log_{10} \left(\frac{1}{\text{risk}} \right) \right|$

As found from this formula, the sample size will often not be a whole number. It is best to round up to the next higher whole number, rather than round to the nearest whole number.

The acceptance number is, of course, always zero in this context.

This formula is accurate only for small values of per cent defective, say, not greater than 10, but this is not disadvantageous since it is never wished to consider high values of per cent defective for critical defects anyway.

If the formula were used for, say, 20 % or 50 % defective, it would over-estimate the sample size needed.

Example : For a certain product, inspection for critical defects is destructive, and it is decided that if a lot were to contain as many as 2 % of critical defectives a risk of only 1

1) This is an extract of clause 9 of ISO 2859/Addendum 1.

in 10 000 should be taken of failing to find a defective in the sample. The formula gives

$$\text{Sample size} = \frac{921{,}04}{2} = 460{,}52$$

The sampling plan for criticals is :

Sample size : 461

Acceptance number : 0 defective

Rejection number : 1 defective

An alternative plan for critical defects, where the defect is something that can be measured rather than a pure attribute, is to sample with a safety margin. Thus, if the minimum allowable breaking load for some component were 2 000 kg, it might be possible, instead of saying that the limit was 2 000 kg and the defect was critical, to say that the limit was 2 500 kg and the defect was major. Just where the limits should be set, and what plan is allowable, depends upon some past knowledge of the amount of variability observed in the strength of the components in question. When this approach is possible, it can give much more satisfactory results for all concerned than seeking for critical defectives (and hoping that there are none present) can do.