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**Milk and milk products — Sampling —
Inspection by attributes**

Lait et produits laitiers — Échantillonnage — Contrôle par attributs

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Contents

Foreword	iv
Introduction	vi
1 Scope.....	1
2 Normative references	1
3 Terms and definitions	1
4 Sampling plans.....	2
5 Selection of sampling plan.....	2
5.1 Classification of defects	2
5.2 Choice of inspection level and AQL.....	3
6 Records	4
7 Selection of units	4
Annex A (normative) Statistical theory	11
Annex B (normative) Critical defects	12
Annex C (informative) Drawing of samples	14
Bibliography	20

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 5538|IDF 113 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*, and the International Dairy Federation (IDF), in collaboration with AOAC International. It is being published jointly by ISO and IDF and separately by AOAC International.

This edition of ISO 5538|IDF 113 cancels and replaces ISO 5538:1987, of which it constitutes a minor revision. Only editorial changes have been made.

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Foreword

IDF (the International Dairy Federation) is a worldwide federation of the dairy sector with a National Committee in every member country. Every National Committee has the right to be represented on the IDF Standing Committees carrying out the technical work. IDF collaborates with ISO and AOAC International in the development of standard methods of analysis and sampling for milk and milk products.

Draft International Standards adopted by the Action Teams and Standing Committees are circulated to the National Committees for voting. Publication as an International Standard requires approval by at least 50 % of the National Committees casting a vote.

ISO 5538|IDF 113 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*, and the International Dairy Federation (IDF), in collaboration with AOAC International. It is being published jointly by ISO and IDF and separately by AOAC International.

All work was carried out by the Joint ISO/IDF/AOAC Group of Experts, *Selection of samples* (E26), under the aegis of its chairman, Mr D.C. Bettes (GB).

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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 be taken at random. If it is not, the sampling plans will not give the stated protection. See Annex A.

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Milk and milk products — Sampling — Inspection by attributes

1 Scope

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.

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.

NOTE Methods of sampling for milk and milk products are given in ISO 707.

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2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 3534-1, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms*

ISO 3534-2, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1, ISO 3534-2 and the following apply.

3.1

acceptance quality limit

AQL

quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling

[ISO 2859-1:1999, definition 3.1.29]

4 Sampling plans

ISO 2859-1 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 acceptance quality limit (AQL).

5 Selection of sampling plan

5.1 Classification of defects

5.1.1 General

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.

5.1.2 Critical defect

This is a defect that would make the product unacceptable. For the purposes 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. 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.

5.1.3 Major defect

This is a defect 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 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, and
- 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 %.

5.1.4 Minor defect

This 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, and
- b) small abnormalities in appearance.

Sampling plans for minor defects shall be selected from Tables 1 to 24 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 Tables 1 to 24, using the lot size and the agreed AQL.

In these Tables, n is the sample size, A_c is the acceptance number, and R_e is the rejection number.

EXAMPLE For a sample size of $n = 13$, $A_c = 0$ and $R_e = 1$, 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 20 are derived from ISO 2859-1 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 may or must be tolerated. As a consequence of using these special levels, there is an increased probability of making a wrong decision. First, the consumer's risk increases. This is illustrated in Tables 21 to 24. Table 21 refers to plans with an AQL of 2,5 %, Table 22 to an AQL of 4,0 %, Table 23 to an AQL of 6,5 % and Table 24 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, i.e. the acceptance number (A_c),
- minimum number of defective units required in the sample to reject the lot, i.e. the rejection number (R_e), and
- the limiting quality (LQ).

If the sample size is small, the LQ is high; if the sample size increases, the 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 may 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 the 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 2859-1; these relate the probability of acceptance to percent 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 is 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 2859-1 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 Annex C, should be used. 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.

For Tables 1 to 20, 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 1 — Inspection Level I — AQL = 2,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	<i>n</i>	Ac	Re	<i>n</i>	Ac	Re	<i>n</i>	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 2 — Inspection Level I — AQL = 4,0 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	<i>n</i>	Ac	Re	<i>n</i>	Ac	Re	<i>n</i>	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 3 — Inspection Level I — AQL = 6,5 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	<i>n</i>	Ac	Re	<i>n</i>	Ac	Re	<i>n</i>	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 4 — Inspection Level I — AQL = 10 %

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	<i>n</i>	Ac	Re	<i>n</i>	Ac	Re	<i>n</i>	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	3	4	20	3	4	8	2	5
501 to 1 200	32	5	6	32	5	6	13	3	6
1 201 to 3 200	50	7	8	50	7	8	20	5	8
3 201 to 10 000	80	10	11	80	8	9	32	7	10
Over 10 000	125	14	15	125	12	13	50	10	13

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

Lot size	Normal inspection			Tightened inspection			Reduced inspection		
	<i>n</i>	Ac	Re	<i>n</i>	Ac	Re	<i>n</i>	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	5	50	3	6