126

INTERNATIONAL STANDARD

ISO 8243

First edition
1988-02-15

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Cigarettes — Sampling

Cigarettes — Échantillonnage

Reference number
ISO 8243 : 1988 (E)

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.

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 8243 was prepared by Technical Committee ISO/TC 126, *Tobacco and tobacco products.*

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.

Printed in Switzerland

Cigarettes — Sampling

0 Introduction

Existing national standards, rules, regulations and laws were taken into account when preparing this International Standard and two different procedures are described :

— sampling at the point of sale;

— sampling at the producer's premises.

Sophisticated sampling plans are often too expensive to be used. The two procedures in this International Standard are both simple and reliable.

Sampling is normally carried out at one point in time, for example of cigarettes available for distribution from a factory or available on the market on a particular day. When a sample is required which represents cigarettes available over an appreciable period of time (e.g. cigarettes representing several months' production) a number of sub-period samples will be taken at different times and the results combined.

The sampling plan depends upon the purpose of sampling, for example determination of physical properties or of smoke constituents.

Detailed sampling plans are given in the annex.

1 Scope and field of application

This International Standard specifies two methods for sampling of cigarettes for the preparation of laboratory samples. Different procedures are specified according to whether sampling is undertaken at the point of sale, at the producer's premises or importer's warehouses.

Either procedure may be used for each of the two methods :

a) At a given time to provide an instantaneous estimate of one or more characteristics of cigarettes. Sampling is carried out within as short a period as possible, not exceeding 14 days. This is called "Sampling at one point in time".

b) Over a period to provide a continuous estimate of one or more characteristics of cigarettes. It can be considered for practical purposes as a series of samples at one point in time. This is called "Sampling over a period of time".

The various possibilities are shown in the table.

2 References

ISO 2602, *Statistical interpretation of test results — Estimation of the mean — Confidence interval.*

ISO 3534, *Statistics — Vocabulary and symbols.*

ISO 5725, *Precision of test methods — Determination of repeatability and reproducibility for a standard test method by inter-laboratory tests.*

Table — Sampling possibilities

Sampling procedure	A		B	
	at the point of sale		at producer's premises or importer's warehouse	
	1	2	1	2
Sampling mode	at one time (instantaneous) (see 4.1)	over a period (continuous) (see 5.1)	at one time (instantaneous) (see 4.2)	over a period (continuous) (see 5.2)
Purpose	any test			

3 Definitions

3.1 sale unit : A quantity of cigarettes ready to be offered for sale to the public. The commonly sold packet of 20 cigarettes is used as the basis of this International Standard, but cigarettes are sold loose and in other size packets.

3.2 population : The aggregate of sale units of the cigarette to be sampled, intended for sale to consumers in a given geographical area in a given time period.

The definition includes different sub-populations, two of which are :

3.2.1 population available to consumers : The aggregate of sale units in retail outlets in a given geographical area, at any time in a given time period.

3.2.2 population manufactured for sale : The aggregate of sale units at a manufacturer's premises available for commercial distribution in a given geographical area at any time in a given time period.

3.3 increment : The sample of cigarettes taken at one time, at one sampling point, to be combined to produce the gross sample.

3.4 gross sample : The aggregate of the increments.

3.5 sub-period sample : That part of the whole sample taken in a brief period when sampling over a long period of time.

3.6 laboratory sample : The sample intended for laboratory inspection or testing and which is representative of the gross sample or the sub-period sample.

3.7 test sample : Cigarettes for test taken at random from the laboratory sample and which are representative of each of the increments making up the laboratory sample.

3.8 test portion : A group of cigarettes prepared for a single determination and which is a random sample from the test sample.

3.9 place of purchase : The town, village or district within the area to be sampled, or that part of the area where the cigarettes are available.

Examples of boundaries are those of cantons, local government districts, electoral areas, postal code areas, or any boundaries according to the geographical context or others.

3.10 sampling point : The specific location (e.g. shop, specialist tobacco shop, vending machine, place in warehouse, place in factory, etc.) from which an increment is to be taken.

3.11 factory : The place of manufacture or its associated distribution depots, or the warehouse of an importer.

3.12 carton : A commercial package available within a factory containing enough packets to provide at least two increments; e.g. packets of 20 cigarettes are usually put into cartons of 200 cigarettes.

3.13 satisfactory cigarettes : Cigarettes of normal production quality with no holes or defects which could cause different results from those which would be obtained from cigarettes in good condition.

4 Procedure for sampling at one time

NOTE — When a sale unit does not consist of a packet of 20 cigarettes, the number of sale units sampled shall be adjusted to produce the required number of cigarettes.

Two alternative sampling procedures are described : in 4.1 a procedure for sampling at the point of sale, and in 4.2 a procedure for sampling at the premises of the manufacturer or importer.

4.1 Procedure for sampling at the point of sale

4.1.1 Selection of the places of purchase

The required number of increments and the number of places of purchase to be used will depend on the purpose of the test and are given in clause A.2 of the annex.

4.1.2 Selection of the sampling points

The increments obtained in each place of purchase shall originate from sampling points which are distributed over separate locations throughout the place of purchase.

The choice of sampling points should, whenever possible, reflect the pattern of retail distribution of cigarettes in that sampling place to be sampled. This is usually done by defining for each sampling scheme several kinds of sampling points (e.g. automatic vending machines, supermarkets, specialist tobacco shops).

Each kind of sampling point is sampled at random throughout the place of purchase, and in total the samples from each kind of sampling point shall make up a defined proportion of the whole sample (this is called a quota from each kind of sampling point).

Sampling shall only be carried out at another kind of sampling point after two unsuccessful attempts have been made at sampling points of the specified kind.

4.1.3 Constitution of the gross sample

The gross sample is the aggregate of the increments. However, for reasons of convenience, it is often preferable to prepare the laboratory sample directly from the increment (3.3) or the sub-period sample (3.5).

4.1.4 Constitution of the laboratory sample

4.1.4.1 If cigarettes are required for several tests on the same population, sufficient sale units shall be obtained from each sampling point. If several laboratories are to run tests, an equal number of sale units from each sampling point shall be contained in each laboratory sample.

4.1.4.2 Each laboratory sample shall be marked with at least the following information :

a) name of the cigarettes and their characteristics;

b) date of sampling;

c) place of purchase;

d) kind of sampling point (if defined);

e) sampling point (address of retail outlet);

f) order number of sale unit of that day;

g) destination (i.e. the laboratory to which the samples are destined);

h) marks on stamp (if any).

4.1.4.3 The cigarettes in the gross sample shall be obtained in as short a time as possible. This time should not exceed 14 days.

4.1.4.4 Pack all the samples securely with adequate protection against damage (e.g. mechanical damage, severe changes in humidity, temperature, etc.) and send them to each laboratory by the most expeditious means.

4.1.4.5 Send to each laboratory, under separate cover, a list of samples dispatched on that day.

4.2 Procedure for sampling at the premises of the manufacturer or importer

4.2.1 Principles

4.2.1.1 Sampling is in general carried out by an independent organization which will send to the manufacturer an accredited person referred to below as "the sampler".

4.2.1.2 Sampling by an outside organization, which shall only be done with the manufacturer's consent unless otherwise required by law, shall be done within given short time periods (days) when the sampler visits the factory. The sampler shall be accompanied by a manufacturer's representative when he is in the factory, unless otherwise required by law.

4.2.1.3 If the manufacturer so requests, the sampler will take a replicate sample for the manufacturer's use (see 4.2.4.1).

4.2.1.4 Samples shall only be taken from the finished product which is ready for commercial distribution. All factories, stock rooms and warehouses containing finished products should be included in the population to be sampled.

4.2.1.5 The sampler shall bring written details of the purpose of test, name of the cigarette and number of sale units. Three copies shall be required : one for the sampler's record, a second to be packed with the samples and a third for the manufacturer to act as a receipt for the goods taken.

4.2.2 Sampling

4.2.2.1 For each increment required, draw one carton (usually 200 cigarettes) at random from the population to be sampled, i.e. at each sampling point selected in the factory.

NOTE — If the population has several strata, e.g. packets from different machine rooms or factories, then the sampling points should be selected from all the strata, in proportion to their respective sizes.

4.2.2.2 If the sampler finds that the stock available is not adequate to take the number of increments required, he shall arrange a further visit to complete the sampling, but samples from different lots shall be considered as different laboratory samples.

4.2.3 Constitution of the gross sample

The gross sample is the aggregate of the increments. However, for reasons of convenience, it is often preferable to prepare the laboratory sample directly from the increment (3.3) or the subperiod sample (3.5).

4.2.4 Constitution of the laboratory sample

4.2.4.1 If cigarettes of the same name and characteristics are required for several tests, sufficient sale units shall be obtained from each sampling point. If several laboratories are to run tests, an equal number of sale units from each sampling point shall be contained in each laboratory sample.

4.2.4.2 Each laboratory sample shall be marked with at least the following information :

a) name of the cigarettes and their characteristics;

b) date of sampling;

c) factory at which the sale unit was taken;

d) sampling point within the factory;

e) order number of sale unit of that day;

f) destination (i.e. the laboratory to which the samples are destined);

g) marks on stamp (if any).

4.2.4.3 Pack all the samples securely with adequate protection against damage (e.g. mechanical damage, severe changes in humidity, temperature, etc.) and send them to each laboratory by the most expeditious means.

4.2.4.4 Send to each laboratory, under separate cover, a list of samples dispatched on that day.

5 Constitution of the test sample

In general, the laboratory sample will contain cigarettes for a number of different kinds of test. Each may require a different size of test sample (e.g. condensate and nicotine can be determined as one test, but determination of cigarette firmness is a separate test requiring a larger test sample). The sample for each kind of test shall contain cigarettes from every increment of the sample, except in the case where the possibility envisaged in 5.1 is used.

For nearly all kinds of tests there will be several individual determinations (replicates, smoking channels) carried out at each laboratory. At some stage, the test sample will be divided into test portions, one for each individual determination.

Each laboratory should arrange its work in the following manner.

5.1 The increments intended to form the laboratory sample are first individually identified. They are then inspected, and if several versions are found (cigarettes with visible differences), they are separated so that separate tests can be carried out on each of them.

5.2 If the laboratory sample is constituted of N increments, and n individual determinations are to be carried out (i.e. n test portions are required), then the increments of any version for which $N < n$ are discarded.

5.3 If the laboratory sample still contains several versions with N_1, N_2, ... increments, divide the n test portions — which will be formed later — between the versions in the proportion $N_1 : N_2 : \ldots$ Within each version divide the increments into test portions of as near as possible equal size (e.g. for 5 determinations and 13 increments, 2 groups of 2 increments and 3 groups of 3 increments).

5.4 Take an equal number of cigarettes from each increment in a group to provide a test portion on which one determination will be carried out. A different number of cigarettes may be taken from increments in another group if it contains more or fewer increments.

5.5 Ensure that each test portion is labelled to show which increments are represented. This information may be needed later for the statistical analysis.

NOTE — If the variability of the sample is required, see clause 7.

6 Procedure for sampling over a period of time

The procedures described in clauses 4 and 5 are concerned with sampling "at one point in time" [see 1 a)].

For some purposes, a sample representing cigarettes available over a period of time (e.g. six months or a year) is required. This can be done by dividing the sample required into a number of sub-period samples which are obtained and tested at different times. It is important that each sub-period sample should be tested at the time of collection and not saved to test the whole sample at the end of the period. This avoids potential problems connected with ageing of the sample and ensures that variations over time in both the cigarettes and the laboratory determinations are taken into account in the measure of sample variability.

6.1 Procedure for sampling over a period of time at the point of sale

The time period shall be divided into at least five equal sub-periods and one sub-sample taken in each sub-period. The number of increments to be taken for the sample shall be the same as that required for a sample at one point in time and they shall be divided equally between the sub-period samples.

When there are many places of purchase in the area to be sampled, each increment of a test portion shall be obtained in a different place (sampled at random, with replacement for each test portion). If, however, such a sampling scheme were very expensive (e.g. if a sampler had to travel to each place specially), a sampling plan for the whole sample could be set up at the start (as for a sample at one point in time) and divided between the test portions in an economical way.

The details of selection and constitution are otherwise as set out in clause 4.

6.2 Procedure for sampling over a period of time at the premises of the manufacturer or importer

The time period shall be divided into at least five equal sub-periods, and one sub-period sample taken in each sub-period from every factory (or importer's warehouse) where the cigarettes are made (or imported). Whenever possible, the number of sub-periods multiplied by the number of factories should equal the number of increments required in the bulk sample. The total number shall be the same as that required for a sample at one point in time, and they shall be equally divided between sub-periods.

At each factory, no more than one increment shall be drawn from a sampling point. Sampling points shall be selected from all the possible sampling points in the factory, with replacement for each sub-period sample as in 4.2.2.1.

Principles, selection and constitution are otherwise as set out in 4.2.

7 Statistical evaluation and reporting

7.1 Statistical evaluation

There are many reasons for sampling commercial cigarettes, for example to check that they comply with the specifications marked on the packet, to publish comparative tables and to see whether the yield of one population is higher or lower than another. The statistical evaluation of the results will, therefore, depend on the purposes of the sampling and the users will have to interpret results in the light of those reasons and prepare tables appropriate for their purpose.

This International Standard is concerned only with sampling, and the report from laboratory or sampling organization to users of the results.

This International Standard does not consider problems of comparisons between laboratories, or of predicting results of one laboratory from those at another laboratory. ISO 5725 considers comparisons between laboratories.

ISO 5725 defines various measures of reproducibility and repeatability, but these are concerned with variations between and within laboratories due to testing errors and techniques. They are not directly relevant to sampling variations.

The combined variations of tobacco products and the analytical procedures are high. It is, therefore, strongly recommended when interpreting the results to take into account the confidence interval of the mean values.

7.2 Outliers

In any body of experimental data there might be outliers, observations in which something may have gone wrong to give a faulty result. ISO 5725 describes two tests for outliers, and recommends criteria for rejecting observations. These methods are recommended for use when evaluating the results of cigarette sampling.

7.3 Confidence interval

As samples taken according to this International Standard are not strictly random, the method of ISO 2602 cannot be used to calculate confidence intervals. However, experience has shown that if sampling is carried out according to this International Standard, the confidence interval for condensate and nicotine, with a confidence level of 95 %, can be estimated at ± 15 %, or at ± 20 % if sampling is carried out according to A.2.1.5 and A.3.1. This includes the variations arising from the sampling procedures and from the product itself. In practice, this confidence interval will, however, not be smaller than ± 1 mg for condensate and ± 0,1 mg for nicotine.

8 Sampling report

The sampling report shall include the following particulars :

a) the dates between which sampling was carried out;

b) the area from which samples were drawn (or the area served by the factories sampled);

c) the number of times sampling was carried out and the number of increments sampled;

d) the number of places sampled, principles of factory sampling (detailed tables of number of increments from each factory are not necessary);

e) notes on anomalies, missing or retested values, very variable cigarettes, etc.

f) any details required by the annex.

Annex

Sampling for the determination of mean values of condensate (water- and nicotine-free) and nicotine in smoke

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

A.1 Scope and field of application

This annex establishes procedures for sampling cigarettes which are intended for the determination of the mean values of condensate (water- and nicotine-free) and nicotine.

NOTE — The relevant test procedures are according to :

— ISO 3308, *Cigarettes — Routine analytical cigarette-smoking machine — Definitions and standard conditions.*

— ISO 3400, *Cigarettes — Determination of alkaloids in cigarette smoke condensates — Spectrometric method.*

— ISO 4387, *Cigarettes — Determination of total and dry particulate matter using a routine analytical cigarette-smoking machine — Glass fibre filter smoke trap method.*

— ISO 8453, *Cigarettes — Determination of total and dry particulate matter using a routine analytical cigarette-smoking machine — Electrostatic smoke trap method.*

It is not necessary to refer to any of these standards in order to use ISO 8243.

A.2 Procedure for sampling at the point of sale at one point in time

A.2.1 Selection of the places of purchase

A.2.1.1 If the area in which the cigarettes are sold encompasses more than 20 places of purchase, 2 increments each are to be obtained in 20 randomly selected places of purchase in the area in which these cigarettes are sold.

A.2.1.2 If the area in which the cigarettes are sold encompasses 11 to 20 places of purchase, 4 increments each are to be obtained in 10 randomly selected places of purchase in which these cigarettes are sold.

A.2.1.3 If the area in which the cigarettes are sold encompasses 6 to 10 places of purchase, 8 increments each are to be obtained in 5 randomly selected places of purchase in the area in which these cigarettes are sold.

A.2.1.4 If the area in which the cigarettes are sold encompasses 1, 2, 3, 4 or 5 places of purchase, 40, 20, 14, 10 and 8 increments each are to be obtained in 1, 2, 3, 4 and 5 places of purchase.

A.2.1.5 An alternative sampling procedure to that given in A.2.1.1 to A.2.1.4 can be used. This is independent of the size of the sales area and not at random, but is satisfactory provided the sampling is done in at least 6 sampling points. A total of at least 40 increments shall be obtained, which should, as far as possible, be evenly distributed among the sampling points.

A.2.1.6 Within each place of purchase, sampling points shall be selected according to 4.1.2. Increments shall be selected according to 4.1.4.2.

A.2.1.7 The volume of sampling shall be expressly stated in the report, giving the number of places of purchase.

A.2.2 Constitution of the laboratory sample

The laboratory sample for a test of a population shall comprise at least 40 sale units, at least one unit from each increment, that is at least 800 cigarettes in all.

A.3 Procedure for sampling at the premises of the manufacturer or importer at one point in time

A.3.1 Sampling

To make up each increment required, draw one or more cartons of cigarettes at random from each sampling point to form the necessary increments.

Take the increments from as many sampling points as possible — at least 10 — distributed between the factories where the cigarettes are made or imported as far as possible in proportion to the production at these factories, provided that every factory is sampled.

NOTE — If the population has several strata, for example packets of different size or from different machine rooms, then the cartons should be drawn from all strata in proportion to their respective sizes.

A.3.2 Constitution of the laboratory sample

Take one increment for the test laboratory and, if required, one increment for the manufacturer from each carton. Label the sample packets and the partly emptied carton. The laboratory sample for each test of a population shall comprise at least 800 cigarettes, or at least 40 sale units, divided equally, or as nearly so as possible, among the increments.

A.4 Sampling over a period of time

A sample representing a period of time can be obtained either from the market or from the factory by dividing the sample specified in clause A.2 or A.3 into a number of sub-period samples taken at different times, as specified in clause 6.

A.5 Constitution of the test sample

This depends on the analytical smoking procedure. Some procedures involve smoking 20 cigarettes per trap, whereas others use only 5 cigarettes per trap. The test sample shall comprise sufficient cigarettes for an appropriately planned experiment to be made. It shall, therefore, be not less than 240 cigarettes.