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Cigarettes — Sampling

Cigarettes — Échantillonnage

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Foreword

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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.

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

This second edition cancels and replaces the first edition (ISO 8243:1988), which has been technically revised.

Annexes A and B form an integral part of this International Standard. Annex C is for information only.

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International Organization for Standardization
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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 or importer's and distributor's warehouses.

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

Sampling is carried out either as a single procedure or as part of a series of samplings.

Sampling is carried out "at one point in time", e.g. of cigarettes available for distribution from a factory/warehouse or available at a retail outlet 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, e.g. determination of physical properties or of smoke constituents. Further background considerations on the choice of sampling procedures are given in annex C. It concludes that determinations of smoke yield should be made on the population manufactured for sale, sampled at manufacturers' factories or importers' warehouses; and that because of variations in cigarette manufacture the "sampling over a period of time" mode should be used wherever possible.

Detailed sampling plans are given in annexes A and B.

NOTE 1 Although outside the scope of this International Standard at present, it is recognized that there may be circumstances where it is relevant to the objectives for which test results are required to sample over a period of time at point of sale.

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Cigarettes — Sampling

1 Scope

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

- a) Sampling "at one point in time" provides an instantaneous estimate of one or more characteristics of cigarettes. Sampling is carried out within as short a period as possible, not exceeding 14 d.
- b) Sampling "over a period of time" provides a continuous estimate of one or more characteristics of cigarettes. It can be considered for practical purposes as a series of samples each taken "at one point in time".

Table 1 — Sampling possibilities

Sampling procedures	Sampling mode	
	1 At one time (instantaneous)	2 Over a period (continuous)
A At point of sale	Subclause 4.1	
B At producer's premises or importer's and distributor's warehouses	Subclause 4.2	Subclause 6.1

This International Standard provides information on the statistical treatment of data and provides estimates, based on practical experience of the order of ranking in condensate and nicotine which is present when a product is sampled in accordance with the specified procedures.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publi-

cation, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2602:1980, *Statistical interpretation of test results — Estimation of the mean — Confidence interval*.

ISO 3534:1977, *Statistics — Vocabulary and symbols*.

ISO 5725:1986, *Precision of test methods — Determination of repeatability and reproducibility for a standard test method by inter-laboratory tests*.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 sale unit: A quantity of cigarettes ready to be offered for sale to the public.

NOTE 2 The commonly sold packet of 20 cigarettes is used as the basis of this International Standard, but cigarettes are also 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 or conditioned sample as appropriate.

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 in accordance with 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; e.g. packets of 20 cigarettes are usually put into cartons of 200 cigarettes.

4 Mode for sampling at one time

NOTE 3 When a sale unit does not consist of a packet of 20 cigarettes, adjust the number of sale units sampled to produce the required number of cigarettes.

Two 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 annex A, A.2.

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 shall, whenever possible, reflect the pattern of retail distribution of cigarettes in that sampling place to be sampled.

NOTE 4 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 sample 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 and also representativeness, it is preferable to prepare the laboratory sample directly from the increment (3.3). This is particularly important in order to secure matched laboratory samples when several laboratories are to run tests.

4.1.4 Constitution of the laboratory sample

4.1.4.1 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.

4.1.4.2 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) destination (i.e. the laboratory to which the samples are destined);
- g) marks on stamp (if any);
- h) printed smoke yields (if any);
- i) manufacturer's pack codes (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 d.

4.1.4.4 All the samples shall be packed securely with adequate protection against damage (e.g. mechanical damage, severe changes in humidity, temperature, etc.) and sent to each laboratory by the most expeditious means.

4.1.4.5 A list of samples dispatched on that day shall be sent to each laboratory, under separate cover.

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 shall 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 provided; 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 5 If the population has several strata, e.g. packets from different machine rooms or factories, then the increments should be drawn 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 and also representativeness, it is preferable to prepare the laboratory sample directly from the increment (3.3). This is particularly important in order to secure matched laboratory samples when several laboratories are to run tests.

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/warehouse at which the sale unit was taken;
- d) sampling point within the factory/warehouse;
- 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);

- h) printed smoke yields (if any);
- i) manufacturer's pack codes (if any).

4.2.4.3 All the samples shall be packed securely with adequate protection against damage (e.g. mechanical damage, severe changes in humidity, temperature, etc.) and sent to each laboratory by the most expeditious means.

4.2.4.4 A list of samples dispatched on that day shall be sent to each laboratory, under separate cover.

5 Constitution of the test sample

5.1 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 5.2 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 as described in 5.2 to 5.6.

5.2 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.

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

5.4 If the laboratory sample still contains several versions with K_1, K_2, \dots increments, divide the k test portions — which will be formed later — between the versions in the proportion $K_1: K_2: \dots$. Within each version, divide the increments into test portions of as nearly as possible equal size (e.g. for five determinations and 13 increments, two groups of two increments and three groups of three increments).

5.5 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.

NOTE 6 A different number of cigarettes may be taken from increments in another group if it contains more or fewer increments.

5.6 Ensure that each test portion is labelled to show which increments are represented.

NOTE 7 This information may be needed later for the statistical analysis. If the variability of the sample is required, see clause 7.

6 Mode 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 clause 1 a)].

For some purposes a sample representing cigarettes available over a period of time (e.g. six months or a year) is required and can be obtained 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 be tested at the time of collection and not saved in order 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.

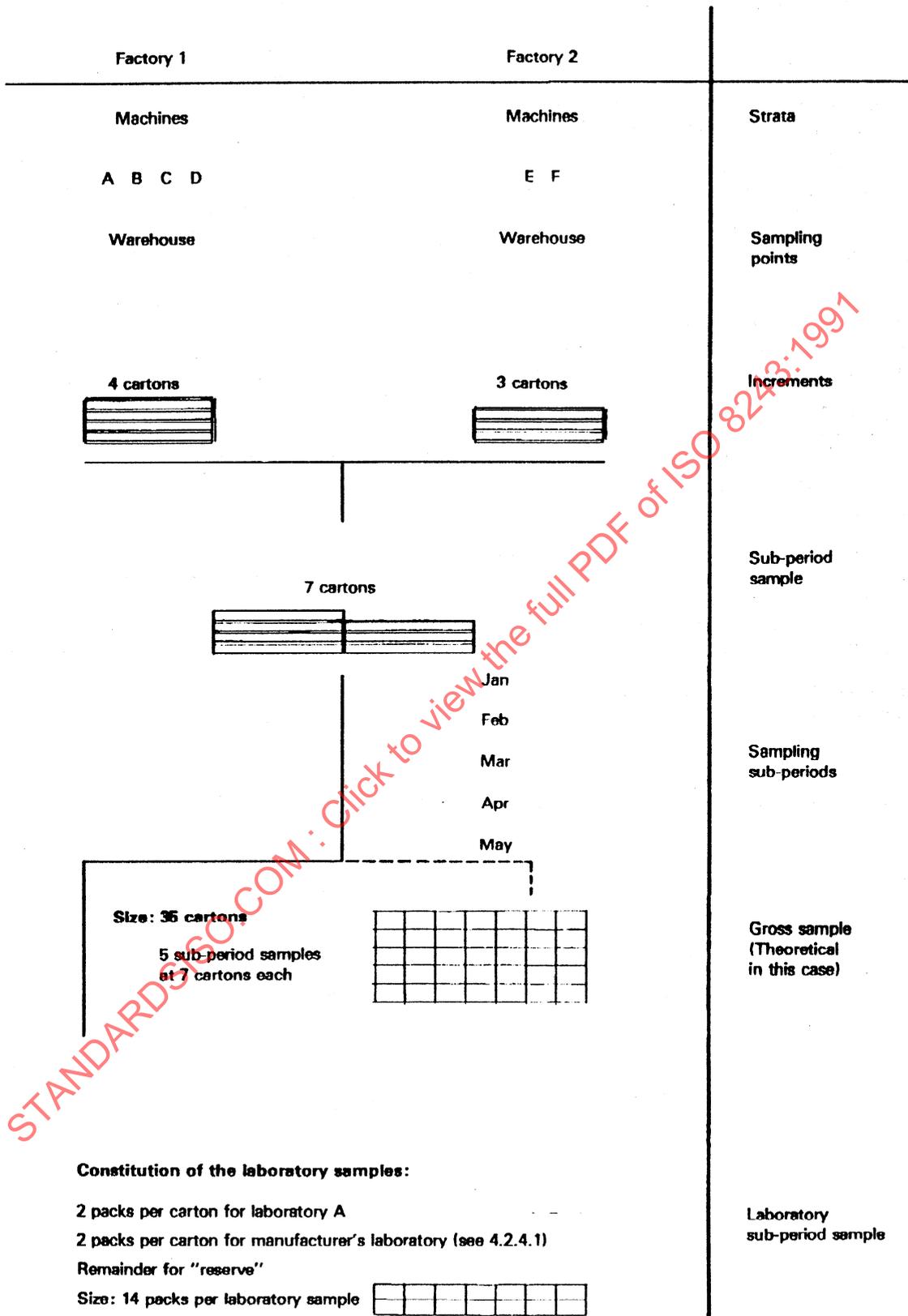
6.1 Procedure for sampling over a period of time at the premises of the manufacturer or importer

The time period shall be divided into at least five equal sub-periods, one sub-period sample taken in each sub-period from every factory (or importer's and distributor's warehouse) where the cigarettes are made (or imported and distributed). Whenever possible, the number of sub-periods multiplied by the number of sampling points 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 sample points in the factory.

Principles, sampling and constitution shall be as described in 4.2.

The procedure of sampling is illustrated in figure 1.



NOTE — Machine E is twice as fast as the other machines, therefore sampling rate is twice as high (see 4.2.2.1).

Figure 1 — Sampling at the manufacturer's premises over a period of time

7 Statistical evaluation and reporting

7.1 Statistical evaluation

NOTE 8 There are many reasons for sampling commercial cigarettes, e.g. to check that they comply with the specification 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 needs.

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

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 (see annex C) and the analytical procedures are important.

NOTE 9 It is 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. The tests for outliers described in ISO 5725 shall be used and its recommended criteria for rejecting observations followed.

7.3 Confidence interval

The method described in ISO 2602 to calculate confidence intervals shall not be used because samples taken according to this International Standard are not strictly random.

However, experience has shown that if sampling is carried out in accordance with 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 in accordance with A.2.1.5 and A.3.1. This includes the variations arising from the sampling procedures and from the product itself. This confidence interval will, however, not be smaller than ± 1 mg for condensate and $\pm 0,1$ mg for nicotine.

8 Sampling report

The sampling report shall include the following particulars:

- a) dates between which sampling was carried out;
- b) area from which samples were drawn (or the area served by the factories/warehouses sampled);
- c) number of times sampling was carried out and the number of increments sampled;
- d) number of places sampled, principles of factory/warehouse sampling (detailed tables of number of increments from each factory/warehouse are not necessary);
- e) notes on anomalies, missing or re-tested values, very variable cigarettes, etc.;
- f) intentional changes to the product, e.g. change in printed smoke yield (C.1);
- g) any details required by annexes A and B;
- h) reference to this International Standard.

Annex A (normative)

Sampling for the determination of mean values of total and nicotine-free dry particulate matter

A.1 Scope

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 10 The relevant test procedures are specified in the following International Standards:

ISO 3308:1991, *Routine analytical cigarette-smoking machine — Definitions and standard conditions.*

ISO 4387:1991, *Cigarettes — Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine.*

ISO 10315:1991, *Cigarettes — Determination of nicotine in smoke condensates — Gas-chromatographic method.*

ISO 10362-1:1991, *Cigarettes — Determination of water in smoke condensates — Part 1: Gas-chromatographic method.*

It is not necessary to refer to any of these International Standards in order to use this International Standard.

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, two 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, four 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, eight increments each are to be obtained in five 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 one, two, three, four or five places of purchase, 40, 20, 14, 10 and 8 increments each are to be obtained in the one, two, three, four or five 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 six sampling points. If used, 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 in accordance with 4.1.2. Increments shall be marked in accordance with 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

From each increment, take portions for the test laboratory and manufacturer (if required) in equal proportions, keeping the remainder as a reserve sample. Label each portion. The laboratory sample for each test of a population shall comprise the greater of 800 cigarettes or 40 sale units, divided equally, or as nearly so as possible, among the increments.

A.3 Procedure for sampling at the premises of the manufacturer or importer and distributor 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 gross sample.

Take the increments from as many sampling points as possible — at least 10 — distributed between the factories where the cigarettes are made or imported and distributed as far as possible in proportion to

the production at these factories, provided that every factory is sampled.

NOTE 11 If the population has several strata, e.g. packets of different size or from different machine rooms, then the increments should be drawn from all strata in proportion to their respective sizes.

A.3.2 Constitution of the laboratory sample

From each increment, take portions for the test laboratory and manufacturer (if required) in equal proportions, keeping the remainder as a reserve sample. Label each portion. The laboratory sample for each test of a population shall comprise the greater of 800 cigarettes or 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 shall be obtained from the factory by dividing the sample specified in 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 to be used. Some procedures involve smoking 20 cigarettes per trap, whereas others use only five cigarettes per trap. The test sample shall comprise sufficient cigarettes for an appropriately planned experiment to be made.

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