International Standard 7002

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

Agricultural food products — Layout for a standard method of sampling from a lot

Produits agricoles alimentaires — Présentation d'une méthode normalisée d'échantillonnage à partir d'un lot

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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.

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 7002 was prepared by Technical Committee ISO/TC 34, *Agricultural food 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.

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Agricultural food products — Layout for a standard method of sampling from a lot

1 Scope and field of application

This International Standard establishes a general layout for standard methods of sampling from lots of agricultural food products.

It gives only general rules for drafting standard methods of sampling. It cannot be used itself, therefore, for sampling products; testing, inspection and acceptance procedures are dealt with to such an extent as to make the user aware of the meaning of further references.

2 General

2.1 Use of the layout

In making use of the layout (see clause 3), it should be remembered that it is for guidance only, and it will have to be adapted in each case to suit individual requirements. Thus, some of the clauses or headings may be omitted in certain instances whilst, in others, additions may be needed in appropriate places to cater for special requirements.

2.2 Plan of the document

In all cases, when drafting a method of sampling, clauses should be arranged in the order given in the layout, if they are to be included in the document.

In this way, the drafter of the method will find it easier to set out systematically all the information needed, with less risk of overlooking any important item. Moreover, the user of the document, knowing that it conforms to this layout, will be able more readily to refer to any clause, whatever may be the origin and scope and field of application of the method. (This is particularly important when considering a partial translation of a method, and in comparing different methods or different versions of a method.)

2.3 Numbering of clauses and sub-clauses

Clauses and sub-clauses shall be numbered consecutively throughout the document, in accordance with the point numbering system described in ISO 2145, *Numbering of divisions and subdivisions in written documents.*

No provision should be made in this sequence of numbers for numbers referring to clauses or sub-clauses of the layout which have not been included in the document (see 2.1).

This consecutive numbering scheme is also recommended when dealing with a broadly based document embracing several methods of sampling, or variants of a given method, constituting different sections of a document.

2.4 Terminology

Use should be made of standardized sampling teminology, including statistical concepts, in particular that given in the International Standards prepared by ISO/TC 69, *Applications of statistical methods*.

In some cases, terms other than those standardized by ISO/TC 69 are used in trade in agricultural food products; definitions relating to the sampling of agricultural food products are given in annex A, and a list of the equivalent English and French terms in annex B. Where traditional usage differs from the standardized terminology, a reference should be made to the standard term, for example by including it as a synonym for the traditional term.

When several synonyms may express the same concept in one of the official ISO languages, preference should be given to that most closely corresponding to the term or terms in the other official ISO languages.

Where there is no similarity of terms in the different languages to express the same concept, and where there exist internationally recognized symbols or abbreviations, these should be used after the terms in the different languages, in order to assist readers of all languages.

2.5 Choice and wording of methods of sampling

As far as possible, the same sampling methods, used as a basis for the assessment of a given characteristic for a given product, should be adopted in all International Standards for related products; the wording used should be as similar as possible. An exception may be made where, in the field in question, this will be contrary to a reasonable and well-established practice which it is desired to retain.

3 Preferred arrangement (for comments on individual headings and clauses, see clause 4)

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4 Rules for drafting individual elements and clauses

NOTE — The following rules supplement those laid down in Parts 2 and 3 of the *Directives for the Technical Work of ISO*.

4.1 Title

The title of the International Standard shall express as concisely as possible, and without ambiguity, the contents of the document, indicating in the following order:

a) the product concerned, in the form in which it figures in the lot to be sampled;

b) the category of samples finally to be obtained, and the purpose for which the sample(s) is/are intended (if specific).

Example:

ISO 6670, *Instant coffee in cases with liners — Sampling.*

4.2 Introduction

The introduction, if any, to the International Standard shall be drafted to suit the user, giving, as appropriate, a short background to the choice of the method selected, and of the layout adopted, together with any other information required for the understanding and use of the International Standard.

4.3 Scope

This clause shall define the content of the International Standard, i.e. the features of the operations called for, and the product or products to which it applies. It shall reflect and amplify the title of the International Standard.

For convenience, this element should be combined with element 4.4 under the heading "Scope and field of application".

Mention shall be made, where appropriate, of the purposes for which the sample(s) is/are required. These may, in particular, relate to one or more of the following purposes of sampling:

a) **commercial purposes**: for example, to procure or prepare a sample:

1) to serve as a basis for an offer for sale,

2) for examination to verify that the material to be offered for sale satisfies the manufacturer's sales specification,

3) for examination as to whether the delivery complies with a contract specification;

b) **technical purposes**: for example, to procure or prepare a sample:

1) for examination to determine one or more of the characteristics of the material, including those affecting health and safety (for example, for foods, the presence of harmful contaminants from agriculture or processing, the presence of bacteria or their metabolites causing various diseases or food deterioration),

2) for quality control or quality inspection during the process of production or manufacture,

3) for control and inspection of the net contents of unit packages,

4) for examination to establish the identity of an unknown material,

5) for examination to confirm the identity of a supposedly known material,

6) for examination to determine, from its characteristics, the source of a given material,

7) to determine the normal and natural composition of materials so that significant deviations may be detected,

8) for examination to verify that a given material is of the type or quality suitable for the purpose for which it is intended or suggested to be used,

9) to monitor the changes in a property with time;

c) **legal purposes**: for example, to procure or prepare a sample:

1) for examination to verify that the material being offered for sale, or for admission to a country, satisfies statutory requirements (consumer protection, hygiene control, etc.),

2) for retention as a reference sample,

3) for examination in connection with criminological investigations,

4) for examination in connection with processes which discharge the material into the surroundings, and for which statutory control exists as to their nature and composition.

NOTE — The preparation of test samples from laboratory samples does not fall within the scope of a method for sampling from a lot.

4.4 Field of application

This clause shall contain all the information required to enable the user to judge whether the International Standard is applicable to the product or products being considered, or whether limitations exist, bearing in mind:

a) the purpose for which the samples are required;

b) the maximum acceptable sampling error if this purpose is to be achieved within the precision limits deduced from, for example, probability levels, using these samples and taking into account the tests to which they are to be submitted.

It shall contain in particular an indication of the product or products to which the method applies, and the limits between which the method can be used without alteration. The limits shall take into account the incidence of variability within the lot and the need, for instance, to insert ancillary operations, such as sorting into sub-lots, and particular examinations on the site or in the laboratory. The various factors to be considered in defining the field of application of the document include the following:

a) intended purpose of the product (for example, direct consumption, raw material, intermediates, process additive, by-product for disposal, or finished material);

b) physical state of the product (for example, liquid, powder, coarse lumps, gas);

c) size of the consignment or lot;

d) whether the method is applicable to bulk or packed material; in the latter case, if necessary, the size, nature and number of containers should also be indicated;

e) the type of examination for which the samples are required (for example, physical, chemical, sensory, bacteriological or combined tests);

f) the level of distribution in trade (for example, wholesale or retail).

4.5 References

This clause shall give a complete list of other documents which are indispensable for the application of the International Standard.

NOTE — This list is not intended to include documents which have merely served as references in the preparation of the standard; such documents can be mentioned, if necessary, in the clause or sub-clause concerned.

4.6 Definitions

The terms used in the document shall be selected as far as possible from those defined in annex A to this International Standard, to which reference shall be made. Any such terms, and any additional terms, shall be given with their definitions in this clause, if it is desired to reproduce them for the convenience of the user of the document, or if they are required for the proper understanding of the text. (See also 2.4.)

4.7 Principle (of the method of sampling)

This clause should briefly define the essential steps of the method to be used, giving the reasons that justify the choice of the particular procedures. The nature of the product to be sampled, the purpose of sampling and an appropriate sampling plan set at the desired level of inspection, often determine the method to be used.

This clause should include the operating characteristic of the sampling plan used, and any assumptions made in calculating this characteristic. The method of sampling selected is dependent on the principle that has been adopted, as well as on the field of application. Examples of different purposes for which sampling is carried out are:

a) sampling to assess the heterogeneity of a bulk lot;

b) sampling to assess the variability between individuals of a lot and the type of frequency distribution in that lot;

c) sampling to assess the mean of a characteristic of a lot;

d) sampling to assess the variability between different parts of a lot (zone sampling, stratified sampling);

e) sampling to assess the number of defects in a lot, taking into consideration the severity of defects;

f) sampling to assess the variability, with time, of a product in movement (continuous, kinetic, or periodic systematic sampling);

g) sampling as part of other more complex schemes such as:

1) quota sampling, which involves, in the case of a heterogeneous lot, taking aliquot parts from each of the several groups constituting a lot,

2) sequential sampling, which involves inspection, testing, or both, as well as sampling.

The reasons shall also include an indication as to whether the method of sampling is based partly or completely on statistical principles, or follows an established scheme of an arbitrary nature based on experience or expediency (composite sample, multiple sampling, multi-stage sampling etc.). Wherever possible, sampling should be based on statistical principles, and if so the estimated or assessed sampling errors shall be stated. To enable the sampling risks to be assessed in the case of products where the distribution of the variable is unknown, an assumption of normal distribution is often made.

4.8 Administrative arrangements

This clause shall briefly indicate the necessary administrative arrangements, if any, to which it is desired to draw the attention of the user of the International Standard.

4.8.1 Sampling personnel

Under this heading, particulars of the number and type of sampling personnel required, including requirements for specialist and supervisory staff, may be given. Where appropriate, an indication of the training and qualifications should be given. In the case of sampling for statutory purposes, attention shall be drawn to the need for officially appointed sampling officers.

NOTE — In certain cases, it may be useful to refer to the existence of specialized sampling organizations which undertake sampling under contract for commercial or arbitration purposes.

4.8.2 Representation of parties concerned

Where the standardized method of sampling is to be used, or may be needed, in connection with enforcement legislation, disputes, arbitration proceedings etc., for which appropriate evidence is necessary of the authenticity of the samples taken, this shall be clearly stated and arrangements for representation of the parties concerned, for witnessing the sampling operations themselves, shall be indicated. Recourse may often be made to independent sampling agents to represent certain parties.

The following are a few examples of the parties, or their agents, by whom representation may be required:

a) owners, manufacturers, processors, producers or vendors, of the product constituting the lot;

b) owners of the container in which the product is stored or transported;

c) transporters of the lot;

d) the insurers involved;

e) the purchasers of the lot.

If sampling is aimed at determining compliance with statutory requirements, sampling shall be carried out in accordance with the terms laid down by government. If the lot is involved in litigation, permission of the authorities may be required for further sampling and for the presence of any of the parties listed.

4.8.3 Health, safety, and security precautions

When appropriate, provision should be made in the International Standard for suitable instructions to minimize any health and safety hazards, and security risks, during sampling. For this purpose, reference should be made to any relevant codes of hygiene or safety concerning the handling of the products in question, and to operations in the area where sampling is to be carried out. Mention should also be made of essential safety equipment, sanitary facilities, etc. Instructions for dealing with spillages, breakages, waste materials, or residues should be provided where necessary, including advice on antidotes, fire-fighting measures, etc. These instructions may affect the marking requirements referred to in 4.13 and 4.14.

4.8.4 Signing of sampling report

Attention should be drawn to the need, in the cases referred to in 4.8.2, for the signing and countersigning of sampling reports by the parties concerned. Moreover, reports issued by sampling officers taking part — on request — in sampling for other than statutory purposes are required to state whether or not the methods by which the samples are taken are in accordance with statutory requirements.

4.9 Identification and general inspection of the lot prior to sampling

This clause should recall the need to:

a) identify the lot in question before any samples are taken, and for this purpose to compare, as appropriate, the number, mass or volume of the lot, and the markings on containers and labels, with the entries on the relevant documents;

b) note any features concerning the condition of the lot and of the surroundings, relevant to the taking of representative samples which are required for the sampling report;

c) segregate damaged portions of the lot and/or, if the lot is unduly heterogeneous, divide it into portions with more similar properties, which will then be treated as separate lots;

d) specify how to mark, if required, individual units or parts of the lot, with consecutive serial numbers for use subsequently in the taking of random samples using random number tables; usually, the numbering of items is arbitrary or a conceptual convenience, but selection of items should be based on the numbering scheme employed;

e) specify the intervals or stipulations on the rules of acceptance or rejection when the relevant sampling methods are applied;

f) specify how to deal with adventitious contaminants that can be easily removed, if desired, before sampling commences, and if necessary retained for examination.

4.10 Sampling equipment and ambient conditions

This clause should specify all the equipment and apparatus required to carry out the specified sampling operations, these items being listed in a logical order.

The equipment or apparatus specified should be suitable for use under the sampling conditions envisaged, and with the product in the physical state in which it is to be sampled. It shall be applied so as to maintain the initial physical state of the product. It should, wherever possible, be equipment or apparatus which is the subject of an existing International Standard and, for this purpose, the reference of the International Standard should be given. Special types of apparatus and their assembly may usefully be illustrated by a diagram or drawing which, in appropriate cases, should be in accordance with the relevant International Standards prepared by ISO/TC 10, *Technical drawings*.

Mention should also be made in this clause of any requirements (for example for sterilization, for the control of the atmospheric conditions, lighting, freedom from dust or draught, etc.) that may be necessary for the efficient conduct of the sampling operations, and for the protection of the product being sampled, including the samples themselves, from any deleteri-

ous effects of the environment. The setting up of the equipment and its maintenance throughout its period of use, during and immediately before and after the sampling, should also be described.

4.11 Sample containers and special packing

This clause should specify all the necessary requirements for the containers in which the samples are to be placed and kept, in relation to their type, size, and suitability for the purpose. This specification may also, therefore, refer to the materials of construction, including their physical and chemical properties, and to the method of closure. Wherever any of these requirements is already covered by an International Standard, the reference should be given. If special packing of the containers after filling is required, for example for temperature control, protection in transit, conformity with statutory regulations, etc., its specification should be given in a clause or sub-clause "Packing samples for storage and/or transport" (see 4.13.3).

When selecting the characteristics to be specified, attention should be given in particular to the following general requirements:

a) Cleanliness of the container (it may be necessary to specify special cleaning, drying, sterilizing, or other treatment, prior to filling with the sample).

b) Quality of the container, in particular:

1) inertness, of all parts of the container, to the sample;

2) suitability for withstanding, where appropriate, the various special treatments mentioned in a);

3) robustness of the container to withstand hazards during the selected method of transport and, if a hazardous material is in the container, compliance with the regulations in force governing its transport, for example in the case of pressure vessels used as containers for the sample, the selection of suitably pressure-tested units;

4) suitability for preserving the sample unchanged for the necessary period, for example by preventing any undesirable access of light, heat, or other radiation, and the passage of moisture or other gases or vapours into or out of the sample;

5) choice of quality of the sample container to hold samples of a given material, depending on the use to which the sample is to be put; for example, while an airtight container may be required for a sample for determining the volatile matter content of the material, a plastic film bag may be adequate for a sample of the same material intended only for particle size analyis.

c) Ullage (headspace) in the container after introducing the sample, including elimination of headspace that might cause unfavourable change in the state of the sample (for example churning of cream).

4.12 Sampling procedures

4.12.1 Sample size

This sub-clause should specify the size and number of samples of each category required (increments, bulk samples, laboratory samples, etc.) in terms of the nature and size of the lot, and in accordance with the terms of lot acceptance if statistical interpretation is needed, and should specify the position in space or time at which the samples are to be taken.

4.12.2 Taking of increments

This sub-clause should give adequate instructions for the operations leading to the collection of all the increments required. Instructions should also be given, if necessary, for the recording of information which will specifically identify individual increments, for the filling of containers (if required at that stage) with these samples, and for the protection or disposal of the portions of the lot which have been sampled.

These operations include the checking and use of the equipment and apparatus, as required, and any other preliminary operations required prior to the actual taking of the increments (for example mixing, melting, etc., of the lot in bulk, or of the contents of individual containers to be sampled).

4.12.3 Preparation of bulk sample, and reduced samples

This sub-clause should describe the production of the bulk sample by bringing together all the increments, followed, if required and if relevant to the product concerned, by blending to produce a homogeneous bulk sample, or by blending and reduction to produce a reduced sample, entailing, as may be required, intermediate operations (mechanical or otherwise) of blending, particle size reduction, and division. The primary blending of increments should of course be avoided when sampling has aimed at the estimation of any heterogeneity of lots or variability of characteristics as referred to in 4.7. If required, provision for the placing of the resulting sample(s) into a container should be included.

This sub-clause should also describe the method of production, and, where appropriate, placing in sample containers, of the required number of as closely as possible identical replicate laboratory samples of suitable size, from the samples obtained as described previously, the number being sufficient for reference, arbitration, contractual, statutory and test purposes.

4.12.4 Selection of samples of prepacked products

4.12.4.1 How to apply sampling plans

The statistical criteria to be used for acceptance or rejection of a lot on the basis of the sample should mainly apply to prepacked products if they have been produced under the conditions of good manufacturing practice (GMP).

Any quality assessment by statistical principles normally requires all data relevant to the product or property concerned, such as the results from plant quality control services rendered

prior to sampling. By means of a systematic disclosure and interpretation of the statistical characteristics (for example process average, standard deviations, distribution of selected properties or homogeneity of lots) of these production data, a suitable sampling plan, or an adaptation to a special case, can be chosen.

Selection of a sampling plan shall take full account of any information which may be available (as previously mentioned) concerning the distribution of the property under consideration. In selecting a scheme from those listed in ISO 2859[1] or ISO 3951[2], due account shall be taken of any special characteristics of the foodstuff or product concerned. Where the schemes are not taken from ISO 2859 or ISO 3951, the subclause should include a full explanation for choosing a different scheme, as the reasons for choosing any sampling plan, including those from International Standards, should always be given.

As a consequence of the various objectives that can exist simultaneously in food sampling, different sampling plans may be needed to estimate commodity defects (attribute plans), net contents (special variable plans), compositional criteria (variable procedures with unknown standard deviation), and health-related properties (for example contaminants, by plans applicable to heterogeneous conditions).

When inspection by variables (ISO 3951) is adopted, preference should be given to plans based on the variance with respect to the most heterogeneous aspect. On advanced level of inspection or at the disposal of sufficient complementary information on the process average, the rules of switching the level of inspection may be introduced. (To give an overview of sampling inspection, a flowchart is presented in annex C.)

4.12.4.2 How to draw samples

When practical, items should be taken in compliance with a random number technique. It is most desirable that any lot should be sampled only once, regardless of the type of sampling applied. Resampling is allowed only in case of spoilage or loss of the items taken.

The withdrawal of items should take place in accordance with that sampling plan which requires the largest number of items. During the sampling procedure, smaller groups of items, intended to yield data for other assessments, should be selected by denoting at random the respective items from that population, as specified in distinct sampling plans. If the mass of such an item is insufficient for multi-purpose examinations, additional items next to it should be drawn.

If possible, take items during handling of the lot (following the expedient exercise of quality control in drawing items from conveyor belts).

In general, sampling plans at the usual level are recommended. When destructive examinations are involved, due consideration should be given to reduced sample sizes (alternative plans). When large samples are drawn, consideration should also be given to mixing and reducing at the sampling site so that excess sample can be returned to the lot.

4.12.4.3 Critical and limiting defects

Sampling methods aimed at inspection for critical defects (for example to obtain evidence of the negligible occurrence of food safety risks) are often applied under heterogeneous conditions.

Critical defects form a special category. The solution generally adopted when non-destructive inspection is involved is to lay down that a sample size equal to the lot size be applied with an acceptance number of zero. If it is ever thought that any particular defect does not warrant this procedure, then serious consideration should be given to having it reclassified as a major defect (see ISO 2859).

Where the only possible inspection for critical defects is destructive (and agricultural food products often fall into this category) a sample which is 100 % of the lot cannot be used. Sample size can be calculated by connecting the percent defective (that quantity of products in which the critical or limiting defect is found once on the average) and the risk we are prepared to take of failing to find a defective (see ISO 2859).

Usually, critical or limiting properties are distributed in an anomalous way; they can only be judged on the basis of inverse J-shaped OC-curves (acceptance number 0). If the forbidden property (essentially it is an attribute) were uniformly distributed, the quality of the lot could be assessed on the basis of a single item.

4.12.4.4 Economic aspects

After the type of sampling plan and the actual sampling method have been decided, it is advisable to estimate the total person-hours per lot in taking and processing the samples and the costs of the overall procedure, including the cost of the sample itself. It will help the parties concerned to balance reliability requirements in relation to economy.

NOTE — **Health and safety precautions**

Special instructions or warnings should be included in the above instructions 4.12.2 to 4.12.4), whenever operations involve hazards to health or safety. (See also 4.8.3.)

4.13 Packing, sealing and marking of samples and sample containers

4.13.1 Filling and sealing of sample containers

This sub-clause shall specify the method of filling, closing, securing and sealing the sample containers, including any special precautions or care to be taken in these operations. It is important that each sample should be unequivocally identifiable. Hence, to avoid any mistake, the sample or the container into which it is to be placed should be given an identification marking immediately before or after the taking of the sample.

1) ISO 2859, *Sampling procedures and tables for inspection by attributes.*

2) ISO 3951, *Sampling procedures and charts for inspection by variables for percent defective.*

Any provisions for the keeping of the sample should be included in this sub-clause, for example:

a) provision of the correct ullage (headspace) in the container;

b) provision of an inert gas or other suitable gas filling the ullage in the container;

c) provision of an inert blanketing liquid around the sample;

d) chemical or physical sterilization or preservation of the contents of the sample container;

e) provision, in special cases, of vented closures to prevent excessive pressure build-up liable to constitute a hazard;

f) provision for ventilation of metabolic products of living tissue (for example, respiration of vegetable products).

4.13.2 Marking

4.13.2.1 This sub-clause should specify the information to be marked on each sample container, or on a label suitably attached to it. If the attachment of a label is not possible, the use of a unique sample number from a previously assigned record book is recommended, with a minimum of identification information, the remainder of the required information being noted on the record form. This information should include:

a) the designation of the material (name, grade, specification);

b) the origin of the material (manufacturer, producer, processor, vendor, contract or order number);

c) the reference of the sampling report;

d) the lot or batch number;

e) the container number;

f) the type of sample;

g) the position from which the sample was taken;

h) the place, date and time of sampling;

i) the sampler's name;

j) any warnings, if required, as to the latest acceptable date for the examination of the sample, or warnings in the case of hazardous material;

k) the destination of the sample.

4.13.2.2 If required, the method of marking the samples may be specified.

NOTE — It is essential to emphasize that stick-on labels should adhere firmly and that they and their markings should retain their function even when contaminated with the sample, and after exposure to the most severe conditions of storage of the sample that can reasonably be expected. If desirable, suitable protective coatings for the labels and marks may be specified.

4.13.2.3 Any special requirements to be marked externally on the packed samples, for the information of the carriers, for example "fragile", "keep cool", "keep refrigerated ... °C", "keep dry", "store away from boilers" should be specified. Any requirements for cautionary markings, for example in the case of hazardous goods, should also be required to be conspicuously shown.

4.13.3 Packing samples for storage and/or transport

4.13.3.1 General

This sub-clause should specify the packing necessary to meet the required conditions of storage (for example refrigerated packs) and to withstand the conditions of transit or transport.

NOTE — A caution should be included that samples of incompatible materials which, if they were to come into contact, would constitute a hazard or otherwise have deleterious effects, for example cause a taint in the case of foodstuffs, should not be packed together in the same container.

4.13.3.2 Packing for dispatch and public transport

4.13.3.2.1 If the material is classified as hazardous, the following should also be specified:

a) the packing required to comply with regulations imposed by the method of transport;

b) any warning labels which may be necessary and/or markings required by transport regulations.

4.13.3.2.2 If the material is a liquid and/or is hazardous the following should also be specified:

a) the quantity and type of material which should be used to absorb and/or neutralize the sample in the event of leakage or breakage;

NOTE — The requirement should ensure that there is sufficient absorbent material under the sample container, whatever its position, to absorb all the sample.

b) if necessary, requirements for an outer liquid-tight package to afford additional protection in the event of leakage or breakage.

4.14 Precautions during storage and transport of samples

This clause should refer to the conditions of storage favourable to the keeping of the sample, and in particular, where appropriate:

a) to control of the ambient conditions to within suitable limits of lighting, temperature, relative humidity, pressure and vibration;

b) to the most suitable position of the container for storage, for example with closure up, with closure down.

In addition, in the case of the majority of products, the maximum shelf-life recommended under these preferred conditions should be stated.

The shelf-life under less favourable conditions may be usefully included for information, if known, but the clause should draw attention to the risks of deterioration of the samples on standing or in transit, as appropriate. It should indicate a maximum storage and transit time in cases where samples may undergo serious irreversible changes (for example non-preserved samples for microbiological examination).

For samples which are to be transported, this clause should contain all instructions or recommendations which may be relevant in the selection of appropriate forms of transport, and in warning the carrier of any hazards to be avoided. Such hazards may include, for instance, problems of spillage, risk of contamination by malodorous substances, damage through shock or vibration. Where such hazards exist, this clause may also refer to the equipment and materials recommended for dealing with them, should they arise.

4.15 Sampling report

This clause should require the preparation of an adequate record of the material sampled and of the method of sampling. Where relevant, it should include details of the condition of the lot sampled and other information resulting from the inspection which is part of the sampler's responsibility. The following subclauses refer to entries, a selection of which may, or should, be called for in the sampling report.

4.15.1 Administrative details

a) the designation and identification of the material sampled;

b) the name and/or grade of the material;

c) the specification of the material;

d) the name of the manufacturer, producer, processor and/or importer, distributor, vendor, etc., as appropriate;

e) the place of manufacture or production, and of receipt;

f) the date of manufacture or production;

g) the manufacturer's or producer's reference or code number, and any other pertinent information appearing on the label (where the inscription is permanent, this should be noted), such as limit date of utilization, list and proportions of ingredients (including additives), etc.;

h) the customer's contract or code number;

i) the total quantity covered by the contract or order;

j) the size and number of units constituting the lot or lots, together with details of markings, or reference to the documents giving this information;

k) the lot or batch numbers;

l) the reference number and date of authority to sample;

m) the place of sampling;

n) the date of sampling and, if required, the interval of time between taking the first and the last increments;

o) the time of sampling and the interval, if any, between taking and packing the samples into closed containers;

p) the names and titles of sampling personnel and witnesses;

q) the identification of the sampling method used, with indications of deviations from the prescribed standard method, if any;

r) the number of samples selected and their identification (marking, with special reference to identification of the seals used, and to batch numbers, etc.);

s) the destination (for example name and address to which samples are sent, or a reference to the consignment note);

t) the date of dispatch of the samples;

u) the atmospheric conditions, for example the weather at the time of sampling, with special reference to relative humidity and temperature, and other measurements where relevant;

v) a statement as to whether the sample is likely to segregate or not in transit or on storage.

4.15.2 Details of unit packs or enclosures containing the lot

These entries should include any relevant observations concerning the containers, enclosure or vessel in which, at the time of sampling, the material constituting the lot was stored or held, for example their physical state and their surroundings.

4.15.3 Material sampled

The relevant entries should incorporate any pertinent observations concerning the material, for example physical state, colour, odour, uniformity, variation between units, presence of visible impurities, foreign matter or separated layers, abnormalities, whether (in the case of a frozen product) there was any evidence of thawing and re-freezing. It should moreover indicate, when necessary, the mass of the sample and whether a preservative has been added to the sample; and an indication of whether sampling was conducted aseptically.

4.15.4 Sampling method

Where the standardized sampling method has been applied, any agreed or essential deviations from the procedure specified should be stated, in the form of a description, including any

serious deviations from the specified ambient conditions; it should also give details of the equipment and/or procedures used, if the standardized method provides only general guidance on these or a range of alternatives.

4.15.5 Marking and sealing of samples

The form in which the samples are presented as individual units, i.e. enclosed or not in sample containers, and how they have been marked and sealed, should be indicated. The type of seal to be used should be stated, together with requirements for the sampler's identification or stamp number, the name of the person who affixed the seal and the names of any official witnesses. Where relevant, the identification used to relate each sample to the part or position in the lot from which it was taken should also be stated.

4.16 Annexes

When it is desirable to relieve the body of the document of detailed information, such information can conveniently be presented in an annex.

Examples are:

a) specifications of apparatus, given as examples;

b) model reports;

c) cautionary notes;

d) references to statutory regulations.

Annex A

Definitions of sampling terms

NOTES

1 The following terms are arranged in English alphabetical order. For comparison, a list of the equivalent English and French terms is given in annex B.

2 It should be noted that traditional usage in the field of agricultural food products has necessitated, in some cases, the adaptation of standardized terms given in ISO 3534, *Statistics — Vocabulary and symbols*.

A.1 acceptable quality level; AQL: For a given sampling plan (see A.43), the quality of a lot (expressed as a true percent variants in the lot in the case of inspection by attributes, and expressed as the true mean value of the inspected characteristic in the case of inspection by variables) that is considered satisfactory as a process average and is associated with a high probability of acceptance (usually 95 %).

NOTE — In sampling by variables, other acceptance criteria may be defined. For example, acceptable quality also may be considered as the quality of a lot expressed as the true mean (see A.23) of the inspected variable often associated with its standard deviation or range that, for purposes of sampling inspection, can be considered satisfactory as a process average.

A.2 acceptance number: For a given attribute sampling plan, the maximum number of variants allowed in the sample that permits acceptance of the lot.

NOTE — In sampling by variables, other acceptance numbers may be defined in terms of the observed values and the permitted tolerances.

A.3 attribute: See A.6, *characteristic*.

A.4 batch: See A.21, *lot*.

A.5 bulk sample:

(1) A collection of increments or groups thereof intended for separate investigation (**raw bulk sample**).

(2) A composite of the increments taken from a bulk lot (**bulk sample** in a proper sense).

(3) A combined aggregation of the items or portions of items taken from a lot of prepacked products (**bulked sample**).

NOTE — It is advisable to denote exactly what type of bulk sample is meant.

A.6 characteristic: A property which helps to differentiate between the items of a given lot into acceptable and unacceptable items. The differentiation may be either quantitative (by variables) or qualitative (by attributes).

NOTES

1 Measurable characteristics (variables) may also be converted to an attribute by determining whether the measurement is in a certain range of values.

2 A characteristic may also be a continuous variable and analysed merely for information and further calculations.

A.7 cluster sampling: A method of sampling in which the lot is divided into aggregates (or clusters) of items bound together in some manner. A sample of these clusters is taken at random and all the items within a cluster are included in the sample.

A.8 composite sample: A sample consisting of portions from each unit, taken in proportion to the quantity of product in each unit selected.

NOTE — Equal portions, the size of which should be specified beforehand, may also be taken from each unit.

A.9 consignment: A quantity of some commodity delivered at one time and covered by one set of documents. The consignment may consist of one or more lots or parts of lots.

A.10 consumer's risk: For a given sampling plan, the probability of acceptance (usually, in the region of 10 %) of a lot having the limiting quality level (see A.20).

NOTES

1 The probability of acceptance is strongly dependent on the severity of defects (see A.12); the more hazardous the defect is to health, the lower the probability of acceptance.

2 *Consumer* may also be taken to mean *buyer* or *purchaser*.

A.11 continuous sampling: Sampling inspection by attributes applied to a continuous flow of individual units of product (see A.18, *item*) that

a) involves acceptance and rejection on a unit by unit basis;

b) employs alternate periods of 100 % inspection and sampling, depending on the quality of submitted product.

NOTE — The procedure can also apply to sampling by variables and to bulk products.

A.12 defective item: An item containing one or more defects.

NOTE — **Defect** means a failure of a unit to meet one or more of the specified requirements.

In the order of significance of the specifications, defects can often be classified as follows:

a) **critical defect**: A defect that, according to judgement and experience, is likely to result in hazardous or unsafe conditions for individuals using, maintaining or depending upon the product, or that is likely to prevent performance of the function of a major product.

b) **major defect**: A defect other than critical, that is likely to result in a failure or to reduce materially the usability of the product for its intended purpose.

c) **minor defect**: A defect that is not likely to reduce materially the usability of the product for its intended purpose or that is a departure from established specifications having little bearing on the effective use or operation of this product.

A.13 homogeneity {heterogeneity}: The degree to which a property of a substance (the observed values of a characteristic) is uniformly distributed throughout a quantity of material (a lot).

In a statistical sense, a lot should be considered homogeneous in relation to a given characteristic if its distribution is assessed to be approximately normal and its standard deviation low. On the contrary, when this distribution is far from normal (for example bimodal) and/or the relevant standard deviation is high, the lot should be considered heterogeneous.

NOTE — Items in a lot may have homogeneous distribution of one characteristic and simultaneously a heterogeneous distribution of another.

A.14 increment: A quantity of material taken at one time from a larger body of material.

NOTE — Increments may be tested individually aiming at estimation of the variation of any characteristic throughout a lot (or between lots). (See also A.5, **bulk sample**.)

A.15 inspection: The process of examining, measuring, testing, gauging or otherwise comparing the unit with applicable requirements.

NOTES

1 *Inspection* may often mean the looking over of the lot.

2 A suitable level of inspection, expressed in statistical or other terms, should be chosen in inverse proportion to the stability of the process average.

A.16 inspection by attributes: A method which consists in taking note, for every item of a lot or of a sample taken from this lot, of the presence or absence of a certain qualitative characteristic (attribute) and in counting how many items have or do not have this characteristic. (Detailed methodology can be found in ISO 2859.)

A.17 inspection by variables: A method which consists in measuring a quantitative characteristic (variable) for each item of a lot or of a sample taken from this lot. (Details of the method are given in ISO 3951.)

A.18 item; individual; unit:

(1) An actual or conventional object (a defined quantity of material) on which a set of observations may be made.

(2) An observed value, either qualitative or quantitative.

A.19 laboratory sample: A sample as prepared for sending to the laboratory and intended for inspection or testing.

A.20 limiting quality; rejectable quality: In a sampling plan, a quality level which corresponds to a specified and relatively low probability of acceptance (usually, in the region of 10 %).

NOTE — This quality level may be specified as the critical number of defectives observed in sampling inspection (i.e. lot tolerance percent defectives) or as a mean of a variable to which the actual mean is compared.

A.21 lot; batch: An identified quantity of some commodity, manufactured or produced under conditions that are presumed uniform.

NOTES

1 *Uniform conditions* have several features, for example products supplied by one producer always using the same production process, where production is stable and the quality characteristic is distributed according to the *normal distribution* (see A.26) or a close approximation to the normal distribution. Specialized subdivisions, etc. can occur.

2 Consequently the term *lot* (or batch) means *inspection lot* [*batch*] in sampling; i.e. a quantity of material or a collection of items (a population) from which a sample is to be drawn and inspected may differ from a collection of units designated as a lot, for example for production shipment.

A.22 lot size: The number of items or quantity of material constituting the lot.

A.23 mean: In ordinary usage, the arithmetic mean; i.e. the sum of n observations divided by n.

NOTE — For a sample of n items taken at random from a lot (see A.34), the mean is an estimation of the true mean m of a random variable which would result from measuring this characteristic in question on the totality of the items. (Also see A.50, *variance*.)

A.24 multiple sampling: Sampling inspection in which sets of replicate items up to a specified sum are taken. After examining one set, a decision can be made to accept the lot, to reject it or to examine another set. Subsequent decisions are

based on an increasing sum of items, associated with decreasing rate of growth of acceptance number. Having inspected the last set, a decision to accept or reject the lot must be reached.

NOTE — The sets of intact items are intended for reference purposes.

A.25 multi-stage sampling; nested sampling: A type of sampling in which a sample is selected by stages, the sampling units at each stage being subsampled from larger units chosen at the previous stage.

A.26 normal distribution: The probability distribution of a continuous random variable, x, of which the probability density is

$$f(x) = \frac{1}{\sigma\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{x-m}{\sigma}\right)^2\right], \quad -\infty < x < +\infty$$

where

σ is the standard deviation of the normal distribution;

m is the expectation (the mean of the variable).

NOTES

1 Theoretically, the normal distribution is the limit value of the binomial distribution, when the variable runs between $-\infty$ and $+\infty$.

2 Other types of distribution function are applied when discrete random variables or extreme values are concerned (for example, Poisson distribution, Weilbull distribution, etc.).

A.27 operating characteristic curve; OC-curve: A curve showing, for a given sampling plan, the probability of acceptance of a lot as a function of its actual quality.

A.28 (periodic) systematic sampling: If N items, arranged in the order of production and numbered 1 to N, are considered to constitute a lot, the periodic systematic sampling of n items from this lot consists in taking the items numbered

$$h, \quad h + k, \quad h + 2k, \quad \ldots, \quad h + (n-1)k$$

where h and k are whole numbers satisfying the relation

$$[h + (n-1)k] \leqslant N < [h + nk]$$

h being generally taken at random from the first k whole numbers.

NOTE — The word "periodic" may be omitted where there is no risk of confusion.

A.29 primary sample: A sample taken from a lot during the first stage of multi-stage sampling.

NOTE — Accordingly, the sample taken from the primary sample is called the secondary sample, etc. The final sample is taken during the last stage.

A.30 probability of acceptance: The probability that a lot of a given quality will be accepted by a given sampling plan.

A.31 probability of rejection: The probability that a lot of a given quality will be rejected by a given sampling plan.

NOTE — Although the term *rejection* implies that the lot does not conform to specifications, it does not necessarily prevent the sale of the lot.

A.32 producer's risk: For a given sampling plan, the probability of rejection (usually, in the region of 5 %) of a lot having an acceptable quality level.

A.33 quality control; quality inspection: The set of operations (programming, co-ordinating, carrying out) intended to maintain or to improve quality, and to set up the production at the most economical level which allows for consumer satisfaction.

A.34 random sampling; simple random sampling: The taking of n items from a lot of N items in such a way that all possible combinations of n items have the same probability of being chosen.

NOTES

1 Random selection can never be replaced by ordinary haphazard or seemingly purposeless choice; such procedures are generally insufficient to guarantee randomness.

2 The phrase *random sampling* applies also to sampling from bulk or continuous materials but its meaning requires specific definition for each application.

A.35 reduced sample: A sample obtained from a bulk sample by reducing its quantity without change of composition.

NOTES

1 It may also be necessary to reduce the particle size in the course of reducing the quantity.

2 Usually, most laboratory samples, reference samples, and storage samples (i.e. the so-called "final samples" in the traditional meaning of the term) can be prepared in this way.

A.36 reference [referee] [umpire] sample: A sample prepared at the same time, and having the same properties, as the laboratory sample, and which is acceptable to the parties concerned and retained for use as a laboratory sample if a disagreement occurs.

NOTE — Although reference samples are expected to be identical with laboratory samples, often the only thing replicated is the act of taking a physical sample.

A.37 rejectable quality: See A.20, *limiting quality*.

A.38 representative sample: A sample drawn so as to reflect as accurately as possible the properties of interest of the lot (the bias of the sample should be a minimum against the lot) from which it is taken.

NOTES

1 The properties of the sample (percent defective items or defects and/or means of variables with standard deviations) are measured. The procedure is *estimative* if the results are taken to directly estimate the properties of the lot, and *non-estimative* if the specifications relate explicitly to the properties of the sample and only the failure of them to meet the specifications which may result in action relating to the lot.

2 This distinction also reflects the range of diversities in legal concepts as to what extent if at all a sample can be considered representative [taking note in particular of the term *homogeneity* (see A.13) of lots].

A.39 sample (general term): One or more items (or a portion of material) selected in some manner from a population (or from a larger quantity of material). It is intended to provide information representative of the population, and, possibly, to serve as a basis for a decision on the population or on the process which had produced it.

A.40 sample size: The number of items or quantity of material constituting the sample.

A.41 sampling: The procedure used to draw and constitute a sample.

A.42 sampling error: That part of total estimation of error of a characteristic due to the heterogeneity of the characteristics, the random nature of sampling and to known and acceptable deficiencies in the sampling plan.

NOTE — Total estimation error is chiefly built up from sampling error and analytical error. The rate of the latter can usually be tolerated if it amounts to only one-third of the sampling error (in the case of major components).

A.43 sampling plan: The predetermined procedure for the selection, withdrawal and preparation of samples from a lot to yield the required information so that a decision can be made regarding the acceptance of the lot.

NOTE — Considerations of cost, effort and delay usually determine an acceptable sampling error.

A.44 sequential sampling: A type of sampling which consists in taking successive items, or sometimes successive groups of items, but without fixing their number in advance, the decision to accept or to reject the lot being taken as soon as the cumulative result permits action, according to rules laid down in advance.

A.45 standard deviation: The positive square root of the variance (see A.50).

A.46 stratified sampling; zone sampling: The sampling of a lot which can be differentiated into sublots (called strata or zones), in such a way that specified proportions of the sample are drawn at random from the different strata.

A.47 test sample: A sample prepared from the laboratory sample according to the procedure specified in the method of test and from which test portions will be taken.

A. 48 variability: The differences throughout the lot in the value of an observed characteristic.

A.49 variable: See A.6, *characteristic*.

A.50 variance: A measure of dispersion based on the mean squared deviation from the arithmetic mean.

NOTE — Depending upon the cases considered, it may be advantageous to divide the sum of the squared deviations from the arithmetic mean by the number of deviations minus 1.

Thus for a series of n observations $x_1, x_2, \ldots x_n$, with mean

$$\bar{x} = \frac{1}{n} \sum_{i=1}^{n} x_i$$

the expression

$$\frac{1}{n-1} \sum_{i=1}^{n} (x_i - \bar{x})^2$$

would normally be used to express an estimate of the population variance obtained via sampling. It is generally denoted by s^2.

If there is some theoretical concern to express entire population variance, the sum of the squared deviations from the arithmetic mean should be divided by the number of deviations:

$$\frac{1}{n} \sum_{i=1}^{n} (x_i - \bar{x})^2$$