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Foreword

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ISO 8086|IDF 121 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*, and the International Dairy Federation (IDF), in collaboration with AOAC International. It is being published jointly by ISO and IDF and separately by AOAC International.

This edition of ISO 8086|IDF 121 cancels and replaces ISO 8086:1986, of which it constitutes a minor revision. Only editorial changes have been made.

Foreword

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

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

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All work was carried out by the Joint ISO/IDF/AOAC Group of Experts, *Sampling techniques for milk and milk products* (E38), under the aegis of its project leader, Mr K. Steen (DK).

This edition of ISO 8086|IDF 121 cancels and replaces IDF 121A:1987. Only editorial changes have been made.

Introduction

The principal reason for checking plant hygiene is to ensure that the plant will not contaminate the product. However, if contamination has taken place, it is possible to discover where in the circuit bacteriological infection, chemical contamination or contamination from filth has taken place. Such checks will be necessary not only to ensure quality control requirements within the plant but also to ensure compliance of products with legal requirements. Also, the checks give information on the checking and sampling procedures used to endorse the practices adopted to ensure cleanliness of the plant.

There are three types of checks on the effectiveness of cleaning and disinfection for which sampling might be performed:

a) checking all contact surfaces which have to be cleaned after and shortly before the production process, and checking re-usable product containers (bottles, moulds, etc.) which have to be cleaned and which will hold the finished product intended for sale;

b) indirect checking on solutions or methods used for cleansing; such checks will principally concern the different operations carried out to ensure that optimum cleanliness is maintained;

c) checking the raw materials or semi-finished products in the course of preparation or of finished products; in practice, such checks give a good idea of the quality of cleansing but they are ancillary to the quality of the raw material used and, in some cases, to the standard of hygiene of the operators of the plants.

Dairy plant — Hygiene conditions — General guidance on inspection and sampling procedures

1 Scope

This International Standard gives general guidelines for inspection and sampling procedures to be used to check the effectiveness of cleaning and disinfection methods used in dairy plants and receiving stations, including milk-collection tankers.

It deals with

— visual inspection,

— sampling from plant surfaces (product line, bottle washing equipment, containers, etc.),

— re-usable product containers,

— air,

— sampling of water and aqueous solutions other than those added to the product, and

— sampling of raw materials and products.

It does not cover equipment normally installed in farms (e.g. milking machinery or refrigerated bulk milk tanks), nor does it deal with the equally important areas of health and hygiene of personnel, factory environment, internal arrangement of the factory, methods of cleaning, packaging materials brought in new from outside (paper, cardboard, plastic, new bottles, etc.), food ingredients and additives, selection of number of units and treatment of the sample in the laboratory.

The need for sampling is normally considered in the design of plant. It is important that any devices which are included to enable samples to be taken are so designed and fitted that their use results in representative samples being obtained without any adverse effect on the hygienic condition of the plant (e.g. by introducing dead spots in cleaning circuits). Such design is outside the scope of this International Standard.

2 Normative references

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

ISO 707, *Milk and milk products — Guidance on sampling*[1)]

1) Equivalent to IDF 50.

3 General instructions

3.1 The demands for effectiveness of cleansing operations vary from plant to plant depending on management supervision, quality control requirements and the type of production undertaken.

3.2 A cleansing control should not be based solely on the results of microbiological tests even if such checks are clearly of prime importance; other checks (such as visual inspection, smell and touch, chemical and/or physical analysis and intelligent interpretation of records) are important in order not to overlook such factors as visible residues, malfunction of equipment, cleaning residues and corrosion.

3.3 Sampling for microbiological examination should be carried out only by personnel trained in sampling for this purpose.

3.4 The frequency of sampling depends essentially on the type of manufacture, the means of checking available to the organization, and the costs acceptable to the organization in carrying out the checking. In theory, a check should be carried out after each cleansing or at a stated interval when cleansing is continuous during a production run (e.g. the case of a bottle washer), or just prior to recommencement of production. However, in practice, a number of checks are carried out to ensure the quality of the product and those checks provide an indirect check on the efficiency of cleansing. Thus, in practice, the checking of effectiveness of cleansing depends upon the quality assurance for the product, bearing in mind that a deterioration in quality is often due to failure in cleansing.

3.5 Generally, it can be said that the frequency of sampling should be determined by measuring the variability of the process and comparing this with the risk of making non-standard product. The optimum solution to this problem requires a good quantitative knowledge of the process, an understanding of statistical quality control, and deliberate management decisions on the degree of risk which is acceptable.

3.6 It is essential that samples be accompanied by a report which identifies the place, date and time of sampling, including any batch details, and the name and designation of the sampling personnel. Where appropriate, the report should include any relevant conditions or circumstances (e.g. the condition of the product containers and their surroundings, the temperature and relative humidity of the atmosphere, the method of sterilization of the sampling equipment, the location of the sampling point on the equipment, and whether a preservative substance has been added to the samples) and any special information relating to the product being sampled (e.g. difficulty in achieving homogeneity of the product).

4 Inspection and sampling procedures

4.1 Visual inspection

4.1.1 An immediate and important impression of the cleanliness of a production line in a dairy plant can be obtained by visual inspection of the accessible parts of a plant. Included in this are all open containers and those closed with a lid, pipe fittings with their washers and gaskets, powder transport lines, air filters, parts which are operated by mechanical means (e.g. homogenizers, pistons, counting devices, stirrers and pumps) and re-usable product containers.

Visual inspection should allow detection of damage due to corrosion or erosion.

4.1.2 Visual inspection may be carried out using good natural or artificial light. Use of ultraviolet light should be resorted to only rarely because of the hazards involved. If ultraviolet light is used, it is more effective when the plant has been flushed with a fluorescine dye; it is essential to cleanse the plant fully after use of such dyes.

Among many other confirmatory tests, the following may be applied to the surface under examination:

a) a clean spatula may be used to scrape a surface carefully, to demonstrate the presence of a film or residues on improperly cleansed equipment;

b) a piece of clean disposable muslin or tissue paper (moist, if desired) wiped over the inside of a can or over metal surfaces of other equipment will be soiled if the surface is improperly cleansed;

c) no sign of fluorescence should be detectable when the surface is carefully inspected with long wavelength ultraviolet light (340 nm to 380 nm).

4.1.3 Stains, greasy residues, powder, or thin hard films are indicative of inadequate cleansing conditions (e.g. inadequate times, chemical concentrations, flow velocities).

4.1.4 More substantial residues of product indicate poor training or discipline of cleaning personnel and/or inadequate circulation and/or leaking valves. Incomplete drainage of equipment increases the risk of contamination of product with chemicals and microorganisms.

4.1.5 At intervals based on past observations and experience, product pumps and valves should be opened and seals and rubbers inspected, especially if products with a high viscosity are processed. This is important even when cleaning in place (CIP) is fully automated.

It is equally important to inspect at regular intervals the spray cleaning devices of the CIP system to ascertain whether they are working correctly.

If plant must be dismantled for checking, a rinse and disinfection cycle of the section of plant involved should follow reassembly.

4.1.6 Whenever visible residues are found in the equipment, it is essential that the cause be traced and measures be taken to remedy the fault. There is only limited value in a microbiological check of visually dirty equipment. Even if a sample were found to be satisfactory from a microbiological viewpoint, all other consequences of inadequate cleansing should be considered. However, determination of the main composition of the residue by chemical means is often more helpful when it comes to trouble-shooting.

4.1.7 Because visual inspection is the most rapid, cheapest and easiest method of examination, it should be carried out as often as possible, i.e. daily.

4.2 Sampling procedures for equipment

4.2.1 Contact surfaces

Although all product contact surfaces should be checked, many such surfaces are inaccessible and only limited facilities are available for sampling and checking the samples. Therefore, a rigorous selection will be necessary in practice. Particular attention should be given to those places which are difficult to cleanse, for example recesses, elbows, valves, shafts, stirrer paddles, gauges, probes.

Sampling by fixed sampling cocks can often cause contamination of the sample and the results of the examination of such samples should be treated with reserve.

4.2.2 Times of checking

Appropriate times of checking are after the cleansing and disinfection of the processing equipment and shortly before re-use of the processing equipment, to check that it has not become contaminated while out of operation.

4.2.3 Direct methods

The methods for the examination of contact surface infection are numerous, but in a dairy plant where all surfaces should be preferably disinfected if not sterilized, rinse and swab tests are preferred. Swab tests are used for plant and equipment where the rinsing technique is not applicable. Also used is the impression method, where a sterile medium is pressed onto the contact surface, then placed and held in a sterile container and later incubated.

4.2.4 Indirect methods

As an alternative to direct methods (4.2.3), indirect methods may be used, either by sampling and examination of the final rinse water (this may include a check for absence of disinfecting agents) before the start of production, or by sampling the initial processed product passed through the plant and considering that as a "rinse" test of the process line.

In many manufacturing plants, there are large sections of process plant which operate as a unit, and which it is desirable not to dismantle during routine operation and cleansing. Such plant is frequently cleansed automatically and may operate under automatic control (e.g. a UHT production line, tank filling, allocation and emptying). In these cases, dismantling for rinsing, swabbing or other direct methods can cause contamination and such methods should only be attempted when other evidence makes a special investigation necessary.

The preferred method for this type of plant is to sample the first product emerging from the process. However, periodic examination of equipment, as mentioned in 4.1.5, remains necessary.

4.2.5 Rinse method

For rinsing purposes, sterile rinsing solution (e.g. peptone/saline solution, quarter-strength Ringer's solution) is normally dispensed in 500 ml quantities. This quantity will suffice for rinsing most pieces of equipment.

Do not use quantities smaller than 500 ml. If the utensil to be tested will not contain this quantity, leave the surplus rinsing solution in the bottle.

Thoroughly wet, as far as possible, the whole surface of the piece of equipment to be rinsed with the rinse solution. Agitation of the solution by rotary or other movement is necessary for dislodging organisms.

Return the rinse to the bottle. The solution should be examined immediately. If this is not possible, any delay should be kept to a minimum and the sample should be cooled quickly to not more than 4 °C and maintained between 0 °C and 4 °C until examined (in any case within 24 h of sampling, but preferably within 6 h to 10 h).

When halogen-releasing compounds (e.g. sodium hypochlorite) have been applied to any surface, add sodium thiosulfate to the rinsing solution before autoclaving, to give a concentration of 0,05 % (mass fraction).

Either 0,25 g of crystalline sodium thiosulfate ($Na_2S_2O_3 \cdot 5H_2O$) or 1 ml of a 25 % (mass fraction) solution of crystalline sodium thiosulfate may be added to each 500 ml of rinsing solution.

NOTE Where dairy plant has received a final halogen-releasing rinse which cannot be completely drained off, the thiosulfate present in the bacteriological rinse solution can be insufficient to inactivate the residual halogen completely. Even a trace of residual halogen will markedly reduce the numbers of viable bacteria collected by the rinse from the plant and will give a lower count than would have been obtained with excess thiosulfate.

If a product containing a quaternary ammonium compound has been used for cleansing, add 5 ml of a sterile solution of a suitable inactivator to the rinse solution as soon as possible after rinsing. The inactivator is prepared by adding 4 % (mass fraction) of egg lecithin to a 6 % (mass fraction) aqueous solution of a suitable anhydrous condensation product of a long-chain fatty alcohol and ethylene oxide, and stirring the warm mixture until the lecithin is dissolved.

4.2.6 Swab method

4.2.6.1 General

This method is applicable to tanks, heat exchangers, large open surface coolers, butter churns, cheese vats, cocks, agitators, air vents, bottle fillers, etc., which cannot conveniently be rinsed. Swab tests can also provide useful local information in addition to the overall picture given by the rinse test.

4.2.6.2 Apparatus

4.2.6.2.1 Test tubes, of length 250 mm and diameter 25 mm, of heavy borosilicate glass or polypropylene.

4.2.6.2.2 Stainless steel wire, of suitable length (approximately 350 mm) and stiffness (diameter approximately 2,6 mm), formed into a loop at one end, and notched at the other end to hold the ribbon gauze (4.2.6.2.3).

4.2.6.2.3 Ribbon gauze, non-medicated, 50 mm wide.

4.2.6.3 Preparation of swab

Use a swab 50 mm in length, consisting of 175 mm of the gauze (4.2.6.2.3) wound round the notched end of the wire (4.2.6.2.2) and secured with thread.

4.2.6.4 Sterilization of swab

Place the swab in 25 ml of rinsing solution in a test tube, plug with cotton wool or a suitable rubber closure, cover the plug with greaseproof paper and sterilize by autoclaving at 121 °C ± 1 °C for 15 min. To obtain a final quantity of 25 ml of solution, it is necessary to start initially with a larger quantity to allow for evaporation during autoclaving. The actual quantity should be determined by trial and error with each individual autoclave.

The rinsing solution should contain sodium thiosulfate or another suitable inactivator as indicated in 4.2.5.

NOTE Pre-sterilized disposable swabs can also be used, but the results obtained may not be comparable with those obtained according to 4.2.6.3.

4.2.6.5 Procedure

Where possible, examine an area of 900 cm^2. Press the swab with a rolling motion against the side of the test tube to remove excess liquid. Remove the swab and, with heavy pressure, rub back and forth over the area to be examined so that all parts of the surface are treated twice. The second rubbing should be at angle of 90° to the first. Rotate the swab so that all parts of it make contact with the surface under test. Return the swab to the test tube and insert the cotton wool plug or rubber closure.

The swab should be examined immediately. If this is not possible, any delay should be kept to a minimum and the tube with the swabs should be cooled quickly to not more than 4 °C and maintained between 0 °C and 4 °C until examined (in any case within 24 h of sampling, but preferably within 6 h to 10 h).

4.3 Sampling procedures for re-usable product containers

4.3.1 Techniques

For re-usable product containers, a representative sample taken from each batch should be checked.

Usually, the rinse technique (4.2.5) is used for sampling re-usable product containers but, depending on the material, impression and swabbing methods may be used (see 4.2.3 and 4.2.6).

4.3.2 Washed cans (or churns)

4.3.2.1 General

The examination is designed to give information on the condition of washed cans. When the examination is carried out at the premises where the cans were washed, examine them within an interval of not less 30 min and not more than 1 h after washing.

Cans with open seams or containing milky water, easily removable milk solids, or a milkstone layer should be regarded as unsatisfactory.

4.3.2.2 Rinse method

Pour 500 ml of sterile rinsing solution into the lid and then into the can. Replace the lid. Lay the can on its side on a clean floor or on a can roller and roll it so that it makes 12 complete revolutions. Allow the can to stand upright for 5 min and then repeat the rolling. Pour the rinse solution from the can into the lid and then into the original bottle. In transferring the solution to the original bottle, collect as much as possible of the 500 ml.

The solution should be examined immediately. If this is not possible, any delay should be kept to a minimum and the sample should be cooled quickly to not more than 4 °C and maintained between 0 °C and 4 °C until examined (in any case within 24 h of sampling, but preferably within 6 h to 10 h).

The rinsing solution should contain sodium thiosulfate or another suitable inactivator as indicated in 4.2.5.

4.3.3 Washed milk-collection tankers

4.3.3.1 General

The method outlined is designed to give information on the condition of tankers immediately after washing and immediately prior to re-use. Areas to be examined include the lid, hose, valves and surrounding pipework, as well as the barrel itself.

The examination should be undertaken not less than 30 min and within 1 h after washing. A visual inspection should be made as outlined in 4.1.

4.3.3.2 Swab method

See 4.2.6.

4.3.4 Washed milk bottles

4.3.4.1 General

The method outlined is designed to give information on the condition of bottles immediately after washing and immediately before re-use.

4.3.4.2 Sampling

Select bottles for examination immediately after washing and immediately before re-use. Close with suitable sterile closures. After closing, take the bottles to the laboratory as soon as possible.

4.3.4.3 Rinse method

Add 20 ml of sterile rinsing solution to each of the bottles and replace the closure. Use this quantity irrespective of the size of the bottle. Where bottles are taken from a hot section of a machine for special purposes, fit them with a suitable sterile closure and allow them to cool before rinsing. Hold the bottle horizontally in the hands and rotate gently 12 times in one direction so that the whole of the internal surface is thoroughly wetted. Allow the bottle to stand for not less than 15 min and not more than 30 min, and again gently rotate12 times so that the whole of the internal surface is thoroughly wetted.

Return the rinse to its previous container. The solution should be examined immediately. If this is not possible, any delay should be kept to a minimum and the sample should be cooled quickly to not more than 4 °C and maintained between 0 °C and 4 °C until examined (in any case within 24 h of sampling, but preferably within 6 h to 10 h).

The rinsing solution should contain sodium thiosulfate or another suitable inactivator as indicated in 4.2.5.