II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 8 June 2001

laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultry meat

(notified under document number C(2001) 1561)

(Text with EEA relevance)

(2001/471/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 64/433/EEC of 26 July 1964 on health conditions for the production and marketing of fresh meat [1], as last amended by Directive 95/23/EC [2], and in particular Article 10(2) thereof,

Having regard to Council Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultry meat [3], as last amended by Directive 97/79/EC [4], and in particular Article 6(2) thereof,

Whereas:

(1) Operators of meat establishments must conduct regular checks on the general hygiene conditions of production in their establishment.

(2) These checks must cover utensils, fittings and machinery at all stages of production and, if necessary, products. This includes microbiological controls.

(3) For a uniform application the nature of the checks, their frequency, as well as the sampling methods and the methods for bacteriological examination shall be established.

(4) It is appropriate to establish these methods on the basis of the most recent HACCP methodology principles.

(5) The operator of the establishment, the owner or his agent must be in a position, on request from the official service, to inform the official veterinarian of the nature, frequency and results of the checks conducted to this end.

(6) The official veterinarian must regularly analyse the results of the checks conducted by the operator of the establishment on the general hygiene conditions of production in his establishment.

(7) Small meat establishments may have more difficulties in implementing the proposed checks due to financial and human resource constraints, lack of expertise, inadequate infrastructure or other relevant factors. The situation in this respect may objectively differ in the Member States.

(8) It is thus appropriate to provide for the possibility of a longer transitional period in respect of small establishments, subject to the requirement that the Member States making use of this derogation provide the Commission with the information necessary to ensure that implementation shall not create distortions of competition.

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

[1] OJ 121, 29.7.1964, p. 2012/64.
[2] OJ L 243, 11.10.1995, p. 7.
[3] OJ L 55, 8.3.1971, p. 23.
[4] OJ L 24, 30.1.1998, p. 31.

HAS ADOPTED THIS DECISION:

Article 1

1. The operator of a meat establishment shall conduct regular checks on the general hygiene conditions of production in his establishment, by implementing and maintaining a permanent procedure developed in accordance with the following HACCP principles:

(a) identify any hazards that must be prevented, eliminated or reduced to acceptable levels,

(b) identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels,

(c) establish critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards,

(d) establish and implement effective monitoring procedures at critical control points,

(e) establish corrective actions when monitoring indicates that a critical control point is not under control,

(f) establish procedures to verify whether the measures outlined in subparagrahs a to e are working effectively; verification procedures shall be carried out regularly,

(g) establish documents and records commensurate to the nature and size of the business to demonstrate the effective application of the measures outlined in subparagraphs a to f, and to facilitate official controls.

2. As part of the system referred to in paragraph 1, operators of meat establishments may use guides to good practice that have been assessed by the competent authority.

Article 2

The micriobiological checks referred to in Article 10(2) of Directive 64/433/EEC shall be carried out by the operator in accordance with the procedure laid down in the Annex.

Samples should be taken from those sites where risk of microbiological contamination is most likely to occur.

Procedures other than the procedure described in the Annex, may be used when these have been demonstrated, to the satisfaction of the competent authorities, to be at least equivalent to the procedure laid down in the Annex.

Article 3

Member States shall ensure that meat establishments introduce the requirements of this Decision within 12 months from the date of its adoption. Member States may, however, decide to apply a period of up to 24 months for small meat establishments, provided they inform in advance the Commission of the conditions under which they intend to implement this derogation.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 8 June 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX

1. BACTERIOLOGICAL SAMPLING OF CARCASES (CATTLE, SWINE, SHEEP, GOATS AND HORSES) IN SLAUGHTERHOUSES

This guide describes the bacteriological evaluation of the surface of carcases. It covers sampling, processing the samples, and presentation of the results.

SAMPLING METHOD

For the **destructive method** four tissue samples representing a total of 20 cm^2 should be obtained from the carcass after dressing but before chilling commences. Pieces of tissue may be obtained using a sterile cork borer (2,5 cm) or by cutting a slice of 5 cm^2 and maximum thickness of 5 mm off the carcase with a sterile instrument. The samples must be placed aseptically into a sample container or plastic dilution bag at the slaughterhouse, transferred to the laboratory and then homogenised (peristaltic Stomacher or rotary blender (homogeniser)).

If a **non-destructive method** is used, swabs must be moistened prior to collection of samples. 0,1 % peptone + 0,85 %NaCI diluent should be used as a sterile broth for moistening the swabs. The sampling area for swabbing should cover at least 100 cm^2 per sampling site. The swab should be moistened for at least 5 seconds in the diluent and rubbed initially vertically, then horizontally, then diagonally not less than 20 seconds across the entire meat surface delineated by a template. As much pressure as possible should be used. After using the wet swab, the same sampling procedure should be repeated by a dry swab. To obtain comparable results consistency in and thoroughness of the technique must be maintained between samples, carcases and sampling days.

SAMPLING LOCATIONS FOR TESTING OF CARCASES

(see figures)

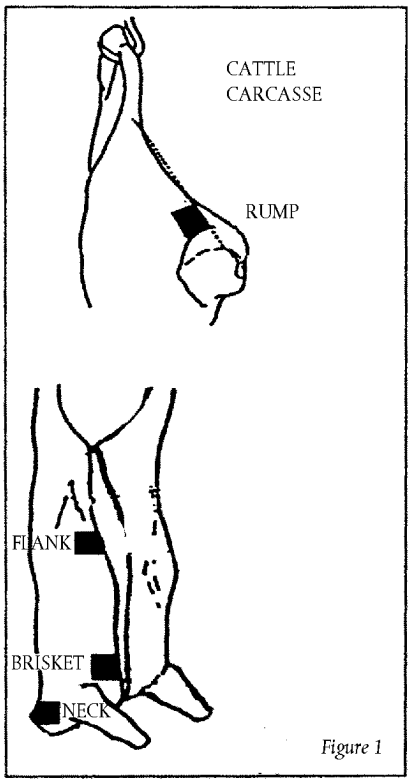

Figure 1

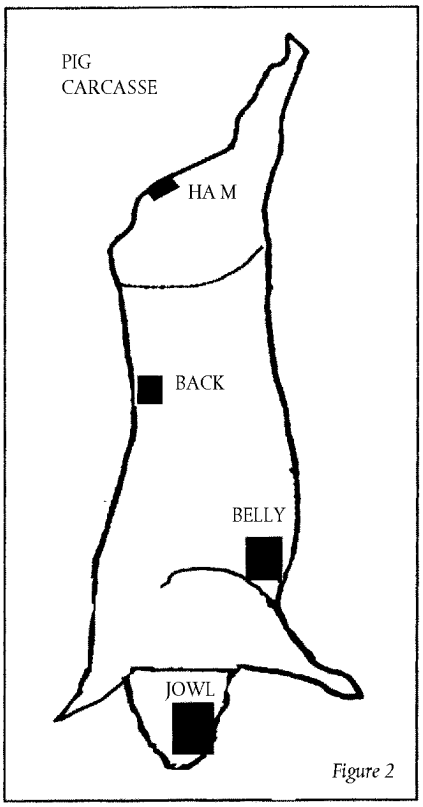

Figure 2

The following sites will usually be appropriate for process control:

Cattle: neck, brisket, flank, and rump (Fig. 1)

Sheep, goat: flank, thorax lateral, brisket, and breast

Pig: back, jowl (or cheek), hind limb medial (ham), and belly (Fig. 2)

Horse: flank, brisket, back, and rump

However, alternative sites may be used, following consultation with the official veterinarian where it has been demonstrated that, because of the slaughter technology at a particular plant, other sites are more likely to carry higher levels of contamination. In these cases sites shown to carry higher levels of contamination may be chosen.

PROCEDURE OF SAMPLING AND NUMBER OF SAMPLES TO BE TAKEN

Between 5 and 10 carcases should be sampled on a single day during each week. The frequency may be reduced to fortnightly testing if satisfactory results are obtained on six consecutive weeks. The day of sampling should be changed each week to ensure that every day of the week is covered. The frequency for testing the carcases in low throughput premises as defined by Directive 64/433/EEC Article 4 and for establishments not working on a full-time basis should be determined by the official veterinarian based on his judgment on hygiene standards with respect to the slaughter at each plant.

A sample from four sites from each carcase should be taken half way through the slaughter day and before chilling commences. Carcase identification, date and time of sampling should be recorded for each sample. Samples should be pooled from the different sampling sites (i.e. rump, flank, brisket and neck) of the tested carcase before examination. Where unacceptable results are obtained and corrective actions do not lead to better hygiene, further samples should not be pooled until dressing problems have been resolved

MICROBIOLOGICAL METHOD FOR THE EXAMINATION OF THE SAMPLES

Samples taken by the destructive method or swabs from the non-destructive method should be stored refrigerated until examination at 4 °C. Samples should be homogenised in a plastic dilution bag for at least two minutes in 100 ml of dilution media (i.e. 0,1 % buffered peptone water, 0,9 % sodium chloride solution) at about 250 cycles of a peristaltic Stomacher or homogenised by a rotary blender (homogeniser). Swab samples may alternatively be shaken vigorously in the dilution media. Samples should be examined within 24 hours after sampling.

Dilution before plating should be carried out in 10-fold steps in 0,1 % peptone + 0,85 % NaCI. The swab suspension and the homogenised meat suspension in the stomacher bag are not a dilution and are to be taken into consideration when calculating as the 10° dilution.

Analysis should be performed for total viable counts and Enterobacteriaceae. However, following approval by the competent authority, and after establishing appropriate criteria, *E. coli* counts may be used instead of Enterobacteriaceae counts.

In addition to the methods described ISO-methods may also provide the basis for examination of samples. Other quantitative methods for analysis of the above mentioned bacteria may be used if they have been approved by CEN or a recognised scientific body, and after approval by the competent authority.

RECORD KEEPING

All test results must be recorded in terms of colony forming units (cfu)/cm² of surface area. To permit evaluation of results records must be shown on process control charts or tables, containing at least the last 13 weekly test results in order. The records should include type, origin and identification of the sample, date and hour of sampling, name of the person that performed the sampling, name and address of the laboratory which analysed the sample, date of investigation of samples in the laboratory and details of the method used including inoculation of different agars, incubation temperature, time, and results as number of cfu per plate used to calculate the result in cfu/cm² of surface area.

A responsible person from the laboratory should sign the records.

The documents should be kept in the establishment for at least 18 months and should be presented to the official veterinarian on request.

APPLYING MICROBIOLOGICAL CRITERIA TO EXCISED-SAMPLE TEST RESULTS (Table 1)

Daily log mean results should be allocated into one of three categories for process control verification: acceptable, marginal, and unacceptable. M and m denote the upper limits for the marginal and acceptable categories for samples taken according to the destructive method.

In order to achieve industry standardisation and to facilitate a valid baseline database, it is imperative to use the most reliable method available. Therefore, it is important to remember, that swab sampling removes only a proportion (often 20 % or less) of the total flora present on the meat surface. Hence, it is only an indicator of surface hygiene.

Where methods other than the destructive method are used, the microbiological performance criteria must be established individually for each method applied in order to relate them to the destructive method, and be approved by the competent authority.

VERIFICATION CRITERIA

The test results should be categorised according to the respective microbiological criteria in the same order as the samples are collected. As each new test result is obtained, the verification criteria are applied anew to evaluate the status of process control with respect to faecal contamination and hygiene. An unacceptable result or unsatisfactory marginal result trends should trigger action to review process controls, discover the cause if possible, and prevent recurrence.

FEEDBACK

The results of the test must be fed back to the responsible staff as soon as possible. The results should be used to maintain and improve the standard of slaughter hygiene. Causes of poor results may be clarified by consultation with the slaughtering staff where the following factors could be involved: 1. poor working procedures, 2. absence or inadequacy of training and/or instructions, 3. the use of unsuitable cleaning and/or disinfection materials and chemicals, 4. inadequate maintenance of cleaning apparatus, and 5. inadequate supervision.

Table 1:

Daily log mean values for marginal and unacceptable results for bacterial performance criteria for cattle, pig, sheep, goat and horse units (cfu/cm²) for samples taken by the destructive method.

	Acceptable range		Marginal range (> m but ≤ M)	Unacceptable range (> M)
	Cattle/sheep/goat/horse	Pig	Cattle/pig/sheep/goat/horse	catle/pig/sheep/goat/horse
Total viable counts (TVC)	< 3,5 log	< 4,0 log	< 3,5 log (pig: 4,0 log) – 5,0 log	> 5,0 log
Enterobacteriaceae	< 1,5 log	< 2,0 log	1,5 log (pig: 2,0 log) – 2,5 log (pig: 3,0 log)	> 2,5 log (pig: > 3,0 log)

2. BACTERIOLOGICAL SAMPLING FOR CHECKS OF CLEANING AND DISINFECTION IN SLAUGHTERHOUSES AND CUTTING PLANTS

The described bacteriological sampling should be applied according to sanitation standard operating procedures (SSOPs) specifying the pre-operational hygiene controls to be carried out in areas which have a direct bearing to product hygiene.

SAMPLING METHOD

This guide describes the contact plate method and the swab technique. The use of these methods is limited to the testing of surfaces, which are cleaned and disinfected, dry, flat, sufficiently large, smooth.

They should always be used before production starts — never during production. If visible dirt is present cleaning should be judged as unacceptable without any further microbiological evaluation.

This method is not suitable for sampling meat or meat products.

Methods offering equivalent guarantees may be used after approval by the competent authority.

AGAR CONTACT PLATE METHOD

For the agar contact plate method, small plastic dishes with lids (i.e. internal diameter 5,0 cm) filled with plate count agar (according to ISO, actual version) and dishes filled with violet red bile glucose agar (VRBG agar according to ISO, actual version) are pressed on to each sampling site and subsequently incubated. The contact surface of each plate is 20 cm².

After preparation the agar has a shelf life of approximately three months when kept at 2 to 4 °C in closed bottles. Shortly before preparation of the plates, the relevant agar has to be melted to 100 °C and cooled to 46 to 48 °C. The plates have to be placed in a laminar air flow cabin and should be filled with agar until a convex surface is obtained. The prepared plates should be dried before use by incubating them upside down overnight at 37° C. This is also a useful check for possible contamination during preparation; plates with visible colonies must be discarded.

The plates have a shelf life of one week at 2 to 4 °C, when sealed into plastic bags.

SWAB TECHNIQUE

Samples should be collected with cotton swabs moistened with 1 ml of 0,1 % NaCI peptone solution (8,5 g NaCI, 1 g trypton casein-pepton, 0,1 % agar, and 1 000 ml distilled water) from a surface area of preferable 20 cm² marked with sterile template. If sampling is performed following cleaning and disinfection an amount of 30g/l Tween 80 and 3g/l Lecithin (or other products with a similar effect) should be added to the moistening solution for swabs. For wet areas dry cotton swabs may be sufficient.

The swabs should be held in sterile forceps and the sampled surface must be swabbed 10 times from top to bottom applying a firm pressure on the surface. Swabs should be collected in a bottle containing 40 ml buffered peptone with 0,1 % agar saline solution. The swab samples must be refrigerated at 4 °C until further processing. The bottle should be shaken vigorously before diluting in 10-fold steps in 40 ml 0,1 % NaCI peptone solution followed by microbiological examination (e.g. drop-plating technique).

FREQUENCY

Always, a minimum of 10 samples or up to 30 samples in a large production area should be carried out within a period of two weeks. Three samples should be taken from large objects. If the results are satisfactory over a period of time the frequency of sampling may be reduced following the agreement of the official veterinarian. Places which should receive most attention are the areas which are destined to come or may come into contact with the product. Approximately two thirds of the total number of samples should be taken from food contact surfaces.

To ensure that all surfaces are tested in the course of a month, a schedule should be made indicating which surfaces should be sampled on which days. The results must be recorded and regular bar charts are to be made to show the developments with time.

TRANSPORT

The used contact plates do not need to be cooled during transport and before incubation.

Swab samples must be cooled until further processing to 4 °C.

BACTERIOLOGICAL PROCEDURES

In addition to the given description, ISO-methods may be used.

The bacterial counts should be reported according to the number of organisms per cm^2 of surface area. Inoculated plate count agar plates and agar contact plates must be incubated for 24 hours at 37 °C ± 1 °C under aerobic conditions for total colony count (TVC). This procedure must take place within two hours of sampling. The number of bacterial colonies should be counted and recorded.

For quantitative estimation of Enterobacteriaceae VRBG agar must be used. Incubation of inoculated plates and agar contact plates must begin within two hours of sampling under aerobic conditions. After 24 h incubation at 37 °C ± 1 °C, the plates must be examined for Enterobacteriaceae growth.

Analysis should be performed for total viable counts. Sampling for Enterobacteriaceae is voluntary unless required by the official veterinarian.

SAMPLING SITES

The following points should, for example, be chosen as sampling sites: sterilisation devices for knives, knives (junction of blade and handle), hollow blood draining knives, elastrators, scalding tanks, bung bagging machines, scraping/gambrelling table (pig), sawblades and cutters, cattle dehiding, other carcase dressing instruments, polishing machine, shackles and containers for transport, transport conveyor belts, aprons, cutting tables, flap doors if touched by passing carcases, chutes for food organs, parts of the line often touched by carcases, overhead structures which may drip moisture, etc.

CALCULATING THE RESULTS

For the agar contact plates and for the TVC and Enterobacteriaceae counts of the swab tests, the results have to be entered on a registration form. For the purpose of process control verification of cleaning and disinfection only two categories for TVC and Enterobacteriaceae have been established: acceptable and unacceptable. The acceptable range for the number of colonies on an agar contact plate and the number of colonies of TVC or Enterobacteriaceae (results from swab tests) are shown in table 2.

Table 2:

Mean values for the number of colonies for testing of surfaces

	Acceptable range	Unacceptable
Total viable counts (TVC)	0 – 10/cm^2	> 10/cm^2
Enterobacteriaceae	0 – 1/cm^2	> 1/cm^2

FEEDBACK

The results of the test have to be reported to the responsible staff as soon as possible. The results should be used to maintain and improve the standard of cleaning and disinfection. Causes of unsatisfactory results should be clarified by consultation with the cleaning staff. The following factors may be involved: 1. absence or inadequacy of training and/or instructions, 2. the use of unsuitable cleaning and/or disinfection materials and chemicals, 3. inadequate maintenance of cleaning apparatus, and 4. inadequate supervision.