AGENCE FRANÇAISE
DE SÉCURITÉ SANITAIRE
DES ALIMENTS

Afssa – Request no. 2007-SA-0174
Related Request no. 2006-SA-0215

Maisons-Alfort, 13 March 2008

OPINION

THE DIRECTOR GENERAL

of the French Food Safety Agency (Afssa) on the references applicable to foodstuffs as process hygiene criteria

The French Food Safety Agency (Afssa) was requested on 12 July 2006 by the Directorate General for Food (DGAl) and the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF), and on 1 June 2007 by the DGAl for an opinion on the references applicable to foodstuffs as process hygiene criteria.

After consulting the "Microbiology" Scientific Panel which met on 6 December 2007 and 11 January 2008, Afssa expresses the following opinion:

Context of the request

As part of the application of the "Hygiene Package" in January 2006, Afssa produced opinions on 20 December 2005 and 24 February 2006 on regulatory changes to the microbiological criteria applicable to foodstuffs. Afssa then received a request on the pathogenic micro-organisms and the opinions produced highlighted the interest of conducting discussions on process hygiene criteria[1].

Afssa therefore received a request from the DGAl and DGCCRF on 12 July 2006 about process hygiene criteria. It was requested to provide the funding government departments with information which could be incorporated into the discussions of government departments and operators as part of their work on guides to good practice for hygiene and for the application of HACCP principles. For this purpose, and as stipulated in the decree of 3 April 2006 on microbiological criteria applicable to products of animal origin and foods containing products of animal origin[2], it was intended to publish references for contamination by the micro-organisms of interest as process hygiene criteria in the form of a notice for operators. This notice for operators is intended to provide a transition between the use of the repealed regulatory criteria and the publication of sector-based Guides to Good Hygienic Practice.

This request was therefore made up of three parts:
1. a request to create reference documents on microbial flora which could be used as process hygiene indicators;
2. a request for an Afssa opinion on the criteria proposed in different sectors, particularly on the interest of the flora adopted and the contamination levels of micro-organisms as process hygiene indicators based on proposals from the professional federations presented in an Excel spreadsheet;
3. a request for instructions for the inspection departments (this information will be the subject of a later request).

In response to the first part of the request, an initial opinion was provided on 18 January 2007 and sent to Afssa's funding government departments. This opinion reviewed the concept of indicators and the qualities required for micro-organism indicators before providing the list of indicators that are mainly used

27-31, avenue
du Général Leclerc
94701
Maisons-Alfort cedex
Tel 01 49 77 13 50
Fax 01 49 77 26 13
www.afssa.fr

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[1] Definition from Regulation (EC) No 2073/2005 of the process hygiene criterion: "a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products once on the market. It sets an indicative value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law".

[2] "Article 5: Pending the construction or revision of good practice guides for hygiene and for application of HACCP principles as stipulated in the aforementioned regulation (EC) No 852/2004 a notice for operators provides references which may be used by operators as process hygiene criteria in their health management plans".

in France in most food industries (excluding water for human consumption). It also indicates how their presence or their presence in excess may be interpreted.

In response to the second part of the request: after examining all of the documents obtained from the professional federations it became apparent that several different microbiological criteria related to similar foods (of different name). As a result, since these proposed criteria had not systematically been harmonised between the federations within the same food sector, their scientific evaluation did not appear appropriate.

In order to begin the expertise, it also appeared necessary that Afssa have access to a far more aggregated document presenting greater harmonisation of the criteria for relevant categories of foods in terms of the risk of microbial contamination from production and retailing processes. This document needed to be validated by professionals in order for the scientific expertise to be based on inter-profession consensual proposals. This request was sent to the professionals via Afssa's funding government departments, by a note dated 27 September 2006.

In June 2007 the DGAl sent Afssa a further request (Request 2007-SA-0174) accompanied by a summary table of the process hygiene criteria proposed by the professionals, organised by production sector and retailing sector.

Expertise method

The mandate of the "process hygiene criteria" working group formed on 23 January 2007 by decision of the Directorate General of Afssa was to produce a scientific opinion on the proposed process hygiene criteria applicable to products that are manufactured and then marketed in France, submitted by the funding government departments and constructed from proposals produced by the professional federations from the different food industry sectors.

This expertise is based in particular on:
- the summary table listing the proposals from the professional federations,
- the original documents sent by the professional federations,
- a document presenting the criteria on which the DGCCRF bases its official controls,
- the DGCCRF's analytical results on different food matrices,
- the regulatory texts and interpretative documents,
- the previous Afssa opinions on microbiological criteria,
- scientific documents of interest which are referenced at the end of this opinion.

Request questions

The experts were asked to:
- **produce an opinion on all of the proposed process hygiene criteria,** and to ensure coherence between the proposals made by successive segments of the same food sector. It may be noted that some food sectors did not offer proposals;

- draft a **didactic review recalling the utility of sampling plans**, their functions and limitations and the major features of the plans most widely used;

- **formulate general recommendations on analytical methods**;

- assess the **practical relevance of using, for** the process hygiene criteria, **the analytical tolerance** limits in interpreting the results, defining a maximum overall standard deviation which is valid for all laboratories depending on the food type tested.

Expert assessment

I. Preamble

Food business operators are required to draw up a sanitary control plan (SCP) under their responsibility, including in particular hazard analysis and factors to manage these hazards produced in accordance with HACCP principles. Microbiological analyses are incorporated into this plan as information to validate/verify the effectiveness of the sanitary control plan. In the past the regulatory criteria have occupied a predominant position within these plans because of their compulsory nature, whether these have been of European (directives, decisions) or national origin.

The sanitary control plans which food business operators must apply may be based on guides to good practice for hygiene and for the application of HACCP principles (GGPH) and incorporate process hygiene criteria, which will have to have been established in light of the hazard analysis and good hygiene practices adopted sector by sector in these guides. However, in most sectors relating to products of animal origin and foods containing such products, GGPH are incomplete, and due to the removal of national criteria, the assessment of self-inspections conducted by operators is now lacking, something that both operators and inspection departments have noticed.

	From 1979 to 2005	From 2006
Microbiological criteria	many microbiological criteria, all set by regulation	few microbiological criteria set by regulation
	no distinction between microbiological safety criteria and microbiological process hygiene criteria	distinction between micro-biological safety criteria and microbiological process hygiene criteria
Action if result unsatisfactory	failure to comply with a microbiological criterion will lead to the conclusion that the foodstuff is unsatisfactory and should be withdrawn from the market or re-used, with tolerances[3] ; beyond $S = 1.000m$ the substance is deemed to be toxic or corrupted	• failure to meet a/comply with? microbiological safety criterion results in withdrawal, recall, reprocessing or re-use • failure to meet a / comply with microbiological process hygiene criterion results in revision of good hygiene practices and of the HACCP system and/or improved selection of raw materials
Taking measurement uncertainty into account in result interpretation	in order to take account of microbiological method-related variations, the analytical results are compared not to *m* but to 3*m* or 10*m* depending on whether the analysis is performed in a solid or liquid medium	the concept of analytical uncertainty associated with analytical techniques is not taken into account in Regulation (EC) No 2073/2005 and there is therefore no tolerance beyond these limits. A Commission[4] document however recommends less strict interpretation of process hygiene criteria limits

[3] see definitions (page 6) of limits *m, M* and *c* from the three-class sampling plan

[4] European Commission Guidance Document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs

Operators' responsibility		operators are encouraged to apply microbiological process hygiene criteria supplementing those in the regulations and to include these in guides to good practice for hygiene and for the application of HACCP principles
		if the operators use microbiological criteria themselves such as those shown in the guides, they do so under their own responsibility

In this transition period it is apparent for operators and their federations, trade unions or inter-professional groups and for the inspection departments that:

- there is a need to take on board all of the changes;
- some operators propose microbiological criteria not to monitor the hygiene of their own processes but to monitor their supplier's hygiene. The stage of the process monitored therefore needs to be targeted with appropriate criteria;
- there is an occasional belief that microbiological monitoring of finished products guarantees their safety and suitability and that inspection can be limited to ensuring that the microbiological criteria are met. However, from now on, the emphasis must be placed by operators on the sanitary control plan (SCP) and by inspection bodies on it's the validation of these SCP and confirmation of their application. In this new context, the results of microbiological analyses provide information which may indicate a lack of hygiene rules, but they are only complementary to the SCP and cannot in themselves guarantee its relevance or application.

Scope of the expert assessment

Afssa was requested only to consider process hygiene criteria which do not appear in Regulation (EC) No 2073/2005. Some regulatory criteria have been incorporated into the summary table provided by DGAl for complementary purposes, particularly for products affected by both types of criteria (regulatory or otherwise).

- Criteria application stage

The process hygiene criteria are intended to be applied at the production and retailing stage for retail establishments in which the products are sold after on site handling (restaurant services, butchery counters, etc.).

Different criteria must be chosen to monitor the hygiene of each of the following three segments of the food chain:

1. Production
2. Transport and interim storage
3. Retailing

The criteria must take account of reasonably predictable changes in microbial flora and be able to detect hygiene anomalies.

For retailing, criteria which relate to specifications (supplier's qualification) and those assessing the retailer's hygiene practices must be distinguished. If retailers have criteria on receipt of merchandise which are different from the supplier's criteria on leaving the factory, this difference should be justified by changes occurring during transport and storage.

- Measures in the event of unsatisfactory results

The operator must define in his/her sanitary control plan the corrective measures which he/she intends to introduce if the criteria are not met, and the conditions through which these will be applied.

For micro-organisms which are both hygiene indicators and pathogens (for example *Clostridium perfringens* and *Bacillus cereus),* operators are recommended to plan for corrections[5] (which may involve a withdrawal/recall procedure in accordance with article 14 of Regulation (EC) No 178/2002). The microbiological limits may be set by companies and included in the GGPH based on records.

[5] Correction: action to eliminate a detected nonconformity (NF EN ISO 22000)

- Microbiological species considered

For pathogenic bacteria, for which the Regulation sets safety criteria for different categories of foods, professionals can set more stringent target levels[6] than the regulatory limits and consider these as hygiene indicators. *Salmonella* can be a process hygiene criterion for foods intended to be cooked provided that it is not used concomitantly with another indicator of faecal contamination such as *E.coli*.
Some professional sectors have also proposed criteria for STEC *E. coli* or pathogenic *Vibrio*. These are pathogenic micro-organisms for which Regulation (EC) No 2073/2005 has not defined a safety criterion to date. In view of their low prevalence, setting a criterion does not ensure that the product is safe. They may however be subject to a withdrawal/recall procedure in terms of article 14 of Regulation (EC) no. 178/2002 because they are harmful to health. They are not therefore relevant as hygiene indicators.

II. Sampling plans: interest and limitations

A. Comments on the sampling plans for the proposed criteria

The sampling plan considered for each of the criteria proposed is a two-class plan, type n=1 (with c=0 and m=M), for all retailing. For the production sector the choice between the use of a 3-class plan with n=5 and c=2, or simple random sampling (where n = 1) to be included in a result monitoring system in the form of control charts or any other equivalent system is left to the companies themselves.

Clearly, the process hygiene and food safety criteria stipulated in Regulation (EC) No 2073/2005 must be observed. As shown below, examining a single unit provides very incomplete information about the microbiological quality of a batch. All of the information obtained from successive batches from the same supplier or same processing unit can, however, provide an estimate of the manufacturer's or processing unit's microbiological quality with increasing accuracy over time. It is also important to understand that uninterrupted compliance with a microbiological criterion by the same supplier or the same processing unit can only occur as a result of continuing hygiene improvement[7]. Under such conditions the practice, common in retailing in particular, of sampling plans with a single unit sample (n=1) appears to be acceptable.

The choice of sampling frequency is the result of a specific compromise for each company. The company must in particular take account of the volume of products manufactured or sold, its confidence in observing hygiene practices in the processing unit or observing the specifications for microbiological criteria given by the supplier and also the company's financial abilities. It is not generally possible to sample all types of foods manufactured in a processing unit. In this situation it is recommended that the type of food which is most liable to be contaminated and/or permit the development of undesirable micro-organisms should be identified and monitoring of compliance of microbiological criteria prioritised for this type of food.

B. Sampling plans used in microbiological criteria: interest and limitations[8]

The sampling plans conventionally used in food microbiology, two- or three-class plans (attribute control plans) were initially defined by ICMSF (International Commission on Microbiological Specifications for Foods) and adopted in particular by the Codex Committee on Food Hygiene (CCFH).

- **Symbols and terms used in sampling plans**

- ***n*:** represents the number of units comprising the sample which needs to be taken randomly from a batch. The value of *n* defines the sample size. Depending on the situation, *n* may be 1, 2, 3, 4, 5, etc. *n* may vary depending on the risk, batch size and occasionally the number of units available.
  A sample size *n*=5 is often used although this value does not represent a rule to be followed in all situations, particularly in testing for specific pathogenic micro-organisms (cf. general comment

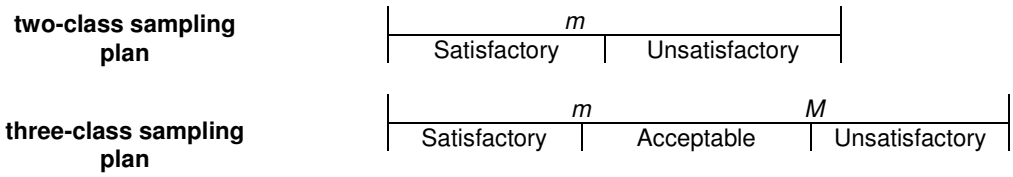
[6] Target level: a more stringent criterion than a critical limit, used by an operator in order to reduce the risk of exceeding a critical limit (NF V01-002)
[7] Cf. Afssa opinion of 25 March 2005 on the draft Community microbiological criteria for Salmonella in minced beef.
[8] According to: *Guidance notes and standards for the interpretation of analytical results in food microbiology,* Committee for establishing food microbiological criteria, Quebec Ministry of Agriculture of Fisheries and Foods, 2006.

below). In these situations the sampling plans recommended by ICMSF and Standard ISO 2859[9] can be used.

- ***m***: the numerical value *m* represents the limit for micro-organism concentrations representing a satisfactory microbiological amount, concentrations which are usually expressed as the number of cfu (colony forming units) per g or ml. In a two-class plan, *m* distinguishes the satisfactory microbiological quality units from unsatisfactory quality units and in a three-class plan, *m* distinguishes satisfactory quality units from acceptable quality units. The numerical values of *m* generally correspond to satisfactory levels through application of good hygiene practices. Non-compliance with the *m* value requires corrective action.

- ***M*** (three-class plans only): represents the unsatisfactory micro-organism concentration limit usually expressed as the number of cfu per g or ml. Failure to comply with this limit represents unacceptable or uncontrolled conditions and/or those carrying a risk to health, depending on the criterion. *M* distinguishes acceptable quality units from unsatisfactory quality units. If the value of a single sample unit exceeds *M* the sample unit or batch from which the sample has been obtained is unacceptable.

- ***c*:** is the maximum allowable number of sample units:
    - of acceptable quality for a three-class plan (i.e. the maximum number of values between *m* and *M*),
    - or of unsatisfactory quality for a two-class plan (i.e. the maximum number of values exceeding *m*).
      If depending on the situation the number of acceptable or unsatisfactory quality units exceeds *c*, the batch from which the sample has been obtained is unacceptable.



- **<u>Two-class sampling plan</u>**

The two-class sampling plan can qualify each sampling unit simply as satisfactory or unsatisfactory. In some plans the presence of a single specific micro-organism such as *Salmonella* is unsatisfactory. In other plans, a limited number of micro-organisms may be satisfactory. In these latter situations a single limit is established and stated per/by? *m*. The two-class plan rejects a batch if the number of units sampled of unsatisfactory quality exceeds *c*. In general, *c* = 0 for pathogenic micro-organisms.

- **<u>Three-class sampling plan</u>**

Sampled units containing less than *m* micro-organisms are deemed to be satisfactory or of good quality. Units containing between *m* and *M* are deemed to be of acceptable quality and units containing more than *M* micro-organisms are unsatisfactory.
The three-class plan rejects a batch:
- if a single sampled unit contains a concentration of more than *M*;
- or if the number of sampled units of acceptable quality is greater than *c*.

- **<u>General comment</u>**

For any sampling plan there is a probability of accepting an "unacceptable batch".
The example below illustrates the uncertainty associated with a two-class plan assuming a homogeneous distribution of the pathogen concerned (for example *Salmonella*) in the batch (which is unlikely the case in solid foods).
The probability of accepting a batch containing positive units for the bacterium studied if 5 sample units (n = 5) are tested and no *Salmonella* positive units are permitted (c=0), is as follows:
- There is a 90% chance of accepting a batch with 2% positive units,

[9] ISO 2859: Sampling rules for attribute controls

- There is a 77% chance of accepting a batch with 5% positive units,
- There is a 59% chance of accepting a batch with 10% positive units,
- There is a 17% chance of accepting a batch with 30% positive units,
- There is a 3% chance of accepting a batch with 50% positive units.

This example illustrates the limited effectiveness of sampling plans with n = 5. If less than 5 sample units are tested the probability of accepting a defective batch increases, and vice versa, when a higher number of sample units is tested the probability of identifying defective batches increases. The characteristics of a two-class plan when n = 1 and c= 0 are shown below:

- There is a 98% chance of accepting a batch with 2% positive units,
- There is a 95% chance of accepting a batch with 5% positive units,
- There is a 90% chance of accepting a batch with 10% positive units,
- There is a 70% chance of accepting a batch with 30% positive units,
- There is a 50% chance of accepting a batch with 50% positive units.

The characteristics of a three-class plan where n = 5, c_m = 2 and c_M = 0 (batch rejection if one or more units exceed limit M = 10m, batch acceptance if less than 2 units are between m and M), when the standard deviation of intra-batch contamination is 0.8 ($\log_{10}$ cfu), are shown below:

- There is a 99.8% chance of accepting a batch containing 2% non-compliant units (of which 1.95% between m and M and 0.05% over M),
- There is a 99% chance of accepting a batch containing 5% non-compliant units (of which 4.81% between m and M and 0.19% over M),
- There is a 96,5% chance of accepting a batch containing 10% non-compliant units (of which 9.43% between m and M and 0.57% over M),
- There is a 72% chance of accepting a batch containing 30% non-compliant units (of which 26.2% between m and M and 3.8% over M),
- There is a 35% chance of accepting a batch containing 50% non-compliant units (of which 39.4% between m and M and 10.6% over M).

III. General recommendations on analytical methods

The following types of analytical methods are recommended in decreasing order of priority when choosing the analytical methods to use for controls to confirm compliance with process hygiene criteria and when there is no specific agreement between the parties:

- AFNOR standardised methods which are identical to CEN and/or ISO standards, or failing this, methods standardised only by AFNOR;

- Commercial methods (commercial kits) provided that these have been validated by AFAQ AFNOR Certification in accordance with Standard NF EN ISO 16140[10];

- In-house methods, provided that these have undergone an appropriate validation. There is at present no standard-based protocol to validate in-house food microbiology methods. Such a protocol will be defined by one of the parts of the future revised version of Standard NF EN ISO 16140. Pending this, the validation dossier should be constructed with reference to the intra-laboratory validation protocols defined in Standard NF EN ISO 16140 for qualitative methods (article 5.1) and for quantitative methods (article 6.2).

In the 2nd and 3rd situations, attention should be paid to ensure the analytical method is actually validated for the couple (micro-organism, matrix) in question.
It should be noted that the new version of Standard ISO 7218[11] envisages the use of one dish per dilution for counting methods. This requirement will apply as soon as the standard is published to all standardised counting methods.

[10] Standard EN ISO 16140 "Food microbiology –Protocol for validating alternative methods"
[11] Standard ISO 7218 "Food microbiology – General rules for microbiological examinations"

IV. Interpretation of results: taking analytical tolerance into account

As a harmonised approach to calculating measurement uncertainty has just been adopted internationally, it is recommended that this be used for the interpretation of analytical results in terms of their compliance with the quantitative limit set for a microbiological criterion.

A. Estimation of measurement uncertainty

For quantitative determinations it is recommended that the general tolerance of 3 times the value of *m* for counts in solid media, introduced in the order of 21 December 1979, no longer be applied but that the approach recently adopted by ISO/TC 34/SC 9 for microbiological analysis of foods described in Technical Specification ISO/TS 19036 and published in 2006 be adopted.

The approach adopted in ISO/TS 19036 is global, experimental and based on total result variability. It takes account of variability associated with the heterogeneity of contamination of the test samples. This variability is quantified by the standard deviation of reproducibility (s_R). ISO/TS 19036 proposes the following three options to estimate the standard deviation of reproducibility s_R [12]:

- intra-laboratory standard deviation of reproducibility, estimated by each laboratory (preferred option);
- inter-laboratory standard deviation of reproducibility, estimated from a method validation inter-laboratory study;
- inter-laboratory standard deviation of reproducibility, estimated from an inter-laboratory performance study.

A number of relatively restricted conditions are recommended in order that the laboratory may use the latter two of these options.

ISO/TS 19036 is not formally applicable to methods based on the most probable number principle, although the approach defined can also be followed for these methods. The small numbers situation[13] is also not considered in the first version of this publication, but will be shortly in an amendment currently being prepared. This will introduce a component associated with distribution of micro-organisms by Poisson's law into the estimation of measurement uncertainty.

B. Information on order of magnitude of measurement uncertainty

Laboratories are invited to estimate their measurement uncertainty for accreditation. They can compare this value with the guideline values provided in the table below. These are average values and it is possible that in specific cases (such as products which contain very heterogeneous amounts of some micro-organisms), these values may not be met. These exceptions should be justified in such situations.

The values in Table 1 have been defined based on (i) results obtained from RAEMA Inter-Laboratory performance studies (Food microbiology analytical and exchange network) organised by ASA[14] (Augustin and Carlier, 2006), and (ii) results of studies which were conducted under the auspices of ISO to estimate the measurement uncertainty component associated with taking a test sample and preparing the stock suspension (Ah Soon and Cornu, 2004). These values are based on thousands of analytical results on the following micro-organisms: mesophilic aerobic micro-organisms, enterobacteria, total coliforms and thermotolerant coliforms, beta-glucuronidase positive *Escherichia coli,* sulphite-reducing bacteria growing in anaerobiosis at 37°C or 46°C, *Clostridium perfringens, Listeria monocytogenes*, coagulase positive Staphylococci, yeasts and moulds, *Bacillus cereus, Pseudomonas, Bifidobacterium,* lactic flora, *Salmonella*. It can be considered that these values are not influenced by the micro-organism tested.

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[12] According to Standard ISO 3534-1, *the standard deviation of reproducibility* is the standard deviation of the results of a test obtained under reproducibility conditions, i.e. results obtained using the same method on identical test samples in different laboratories performed by different operators using different equipment. It should be noted that ISO/TS 19036 adapted this concept to analyses performed in a single laboratory, in which case it introduced the concept of intra-laboratory reproducibility.

[13] i.e. less than 10 colonies counted in at least one dish, which normally represents less than 100 (or 1000) cfu per g or ml, for an inoculum of 1 ml (or 0.1 ml).

[14] Association Animal Société Aliment (Association for animals, society and food)

It has been shown that these guideline values depend mostly on:
- the matrix effect (homogeneous/heterogeneous);
- the number of colonies counted on the dishes (effect due to the distribution of micro-organisms by Poisson's Law);
- the presence or absence of a confirmatory stage in the counting method used;
- and the standard deviation of intra/inter-laboratory reproducibility as defined in ISO/TS 19036 (cf. above, *A*).

According to the ISO tests, the following matrices can be considered to be homogeneous:
- liquids (e.g. milk, water, drinks) and powders (e.g. milk, egg powder);
- solid mixtures (minced meat, mechanically separated meat, sausage meat, ground meat, whipped cream, ice creams, soya cream etc.).

Table 1: Guideline values for analytical tolerance (acceptable measurement uncertainty) for bacterial counts (in log cfu) based on work by Augustin and Carlier (2006) and Ah Soon and Cornu (2004)

	Homogeneous matrix		Heterogeneous matrix	
Total number of colonies counted on the dish(es) used for counting	Method without confirmation	Method with confirmation	Method without confirmation	Method with confirmation
≤ 5	0.7	0.7	0.7	0.8
6-10	0.5	0.6	0.6	0.7
11-15	0.4	0.5	0.5	0.6
>15-150 or 300 depending on the case	0.3	0.5	0.5	0.6

C. Taking measurement uncertainty into account in interpreting results

Regulation (EC) No 2073/2005 states in one preamble that, in order to observe "Article 4 of Regulation (EC) No 852/2004, food business operators are to comply with microbiological criteria (…). It is therefore appropriate to lay down implementing measures concerning the analytical methods, including, where necessary, the measurement uncertainty, the sampling plan, the microbiological limits, the number of analytical units that should comply with these limits". Regulation (EC) No 2073/2005 therefore sets microbiological criteria based on this preamble and stipulates that meeting a criterion implies "the acceptability of a product, a batch of product or a process".
As a result we understand that the criteria appearing in the Regulation take account of measurement uncertainty in such a way that if the limit *m* is exceeded on more than *c* occasions, or limit *M* is exceeded on one occasion, the product, batch of product or process is unacceptable. It is therefore essential that:

$$R + MU \leq m$$

where R is the analytical result and MU is measurement uncertainty.

Example: Coagulase positive Staphylococci in 0.1 mL and 0.01 mL of milk (a homogeneous product) are counted on Baird-Parker medium. Twenty-eight colonies are found (at the -1 dilution) and 5 (at the -2 dilution). For this type of count the laboratory measurement uncertainty is 0.5. The concentration in milk is estimated to be 10 x (28 + 5)/1.1 =300 cfu/mL. The corresponding figure after logarithmic transformation is 2.48. We are seeking to confirm that the limit *m* = 100 cfu/mL is met. The logarithm of this number is 2. As 2.48 + 0.5 = 2.98 is greater than 2, the microbiological limit is not met.

However, the "European Commission Guidance Document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs" states "Indicators are used to determine the acceptable functioning of a production process. Therefore, the rules for interpretation of results of these indicators related to process hygiene criteria in Regulation (EC) No 2073/2005 need not be as strict as in the context of food safety criteria.".

The order of 1979 did not require the limit *m* to be met but set a tolerance of 3*m* or 10*m* depending on the situation. It is reasonable to consider that most professionals when producing their proposals have continued to reason in the spirit of the 1979 order and in the spirit of the guidance document mentioned above, i.e.:

$$R \leq m + MU, \text{ or } R - MU \leq m$$

Example: still using the example above but applying the second rule, 2.48 needs to be compared to 2 + 0.5 = 2.5, or 2.48 – 0.5 = 1.98 to 2. In this case the microbiological limit is met.

The work on incorporating measurement uncertainty into result interpretation will be continued in an Afssa self-request.
It would appear necessary for the following points to be clarified by the European Commission:
- does the word "limit" mean the same whether it is a safety criterion or a process hygiene criterion, incorporating analytical uncertainty in the same way?
- what does "less strict interpretation rules" mean in the European Commission Guidance Document on official controls, concerning microbiological sampling and testing of foodstuffs?

It seems preferable that a consistent position be adopted for all types of criteria, for the word limit to retain its common meaning of a value not to be exceeded.

In view of the uncertainty about incorporating analytical tolerance into the microbiological limits proposed by professionals, the working group experts considered orders of magnitude and not absolute values. The possibility that some of the microbiological limits proposed were developed following the new European vision whereas others were developed according to the old French approach, i.e. implicitly accepting that the results will be compared to 3*m* or 10*m*, cannot be excluded.

V. Analysis of process hygiene criteria proposed by different professional federations from the food industry

Hygiene criteria were proposed in the production and retailing stages for the following categories of foods:
- Raw butchery meats and meat products
- Raw poultry, rabbit and game meat
- Fishery products
- Meat-based products and processed pork products
- Cooked dishes and various freshly produced products (sandwiches, cold snacks, etc.)
- Frozen and deep-frozen products (production stage)
- Cakes and desserts (retail stage)
- Dairy and cheese products
- Raw vegetable products (retail stage)

Difficulties experienced by the working group

The summary tables sent by the DGAl to Afssa are in some cases less complete than those from the federations or contain differences for example in sampling plans. In addition:
- Several proposals from the federations do not consider procedures specific to the operator but suppliers' procedures and because of this the criteria proposed are not always relevant.

- Different federations give different names to the same products. As a result, different criteria are proposed for similar product categories (the working group regrets that the consultation between federations, which Afssa had wanted, did not take place).

- Products are named according to their place of sale and not by their manufacturing process or nature: for example, "delicatessen products".

- Some criteria are redundant: it does not appear, for example, to be useful to monitor several indicators of faecal contamination such as *Escherichia coli* and *Salmonella.*

- The ratios proposed for total flora against lactic flora (100) appeared to be considerably too high to the working group. A value of less than 10 would be more representative of a high performance company in terms of hygiene and cleanliness.

The summary tables showing the proposed criteria are presented in the annex. For most of the criteria proposed, comments are given about the relevance of the micro-organisms, limits and categories of

products concerned. A regrouping of some categories of foods and redefinition of others is proposed. In addition, questions are raised for some federations.

A. Raw butchery meats and meat products

- **Raw beef, minced meat, meat preparations, offal, blood for human consumption in the production stage** (Cf. Annex A.1)

It would be appropriate to harmonise the name or state the flora tested (total flora at 25 or 30°C, aerobic micro-organisms at 30°C; Enterobacteriaceaeat 30°C or 37°C). Also, showing *Pseudomonas* and total flora per gram in the same column does not inform the reader, particularly for vacuum-packed products.
Before making a final decision about these proposed criteria, explanations and further details are required from the federations about:

- The distinction between total flora (25 or 30°C) and aerobic micro-organisms at 30°C;
- The difference in the *E. coli* / Enterobacteriaceaeat 37°C ratio between cut beef pieces (100/1000) and 2nd stage processing offal (100/ 50000);
- The factor of 5 between the limits for Enterobacteraciae in 1st and 2nd stage processing red offal (10,000 and 50,000);
- The Salmonellae criterion status for blood: testing is required if the aerobic micro-organisms at 30°C or Enterobacteriaceae criteria are exceeded.

- **Raw butchery meats and meat products at the retail stage** (Cf. Annex A.2)

A total flora/lactic flora ratio of 100 is proposed for vacuum-packed products and also for minced meats for immediate sale, (tartare, carpaccio, etc). This ratio appears to be very high compared to the total flora of 5,000 000 cfu/g. In view of changes in meat storage methods and the development of bio-preservation, the total flora/lactic flora is of interest. Achieving a value of 100, however, does not appear to be a sign of an effective company in terms of hygiene and cleanliness.

B. Raw poultry, rabbit and game meat

- **Raw poultry and rabbit meat (fresh and frozen) at the production stage** (Cf. Annex B.1)

It is inappropriate to keep the following products in this table:

- stuffed products (sausages, meat skewers, stuffings, minced meats, stuffed escalopes) and marinated products;
- products containing cooked poultry or rabbit (cordon bleu, nuggets, roasted wings);
- processed poultry meats.

Priority must be given to testing for Salmonella in 10 or 25 g.
Before making a final decision about these proposed criteria, explanations are required from the federations about:

- The choice of the criterion *E. coli* for rabbit meat. This is debateable as *E. coli* is not a dominant part of the rabbit intestinal flora;
- The factor of 2 between the microbiological limits for the criteria *E. coli* and coagulase positive Staphylococci for whole and cut pieces with skin from chicken and rabbits and specifically the adoption of a limit of 5000 cfu/g for coagulase positive Staphylococci for skinless products;
- The absence of a criterion for coagulase positive Staphylococci for cut pieces of raw skinless chicken: a criterion which is proposed for cut, skinless rabbit;
- The factor of 100 between the microbiological limits for the criteria *E. coli* in mechanically separated meat (MSM) with low calcium content and MSM with high calcium content, which appears high.

- **Raw game meats in the production stage** (Cf. Annex B.2)

For farmed, small game, the microbiological limit proposed for coagulase positive Staphylococci (5000 cfu/g) appears to be high and needs to be justified. The group recommends the limit of 500 cfu/g from the 1979 order.

- **Raw chicken and rabbit meats in the retail stage** (Cf. Annex B.3)

The microbiological limit proposed for *Pseudomonas* appears to be high and must be accompanied by wording about maintaining organoleptic quality. Similarly, the microbiological limit for the coagulase positive Staphylococci criterion (5000 cfu/g) for whole raw chicken and rabbit with skin appears to be high and needs to be justified.

C. Fisheries products

A change in the proposals for the criteria shown in annex 1.C is proposed in light of the following observations:

- Product names

In the "name" column, the products need to be regrouped. Some products have been separated without real justification leading to an unnecessarily complicated tool being proposed. It should also be made as functional as possible for operators and the proposal has been changed to this effect.

- Consistency with GGPH

The references used as hygiene process criteria which will be published in a notice for operators may help in the production of GGPH. In any event, it is essential that the notice for operators and the GGPH are consistent.

As this involves the "Smoked and/or salted and/or marinated fish" GGPH, which has already been written by professionals and validated by Afssa and the DGAl, this should conversely be taken into account in drawing up the notice for operators. With this in mind, Table 1 incorporates the hygiene criteria and values adopted in the GGPH for these products. The “cooked shellfish” GGPH is currently being written and it should be ensured that this guide is consistent with the notice to operators on the process hygiene criteria.

- Justification of the proposed limits
  - aerobic micro-organisms at 30°C: how is the change from 10,000 to 20,000, or from 100,000 to 200,000 cfu/g justified? In order to avoid such a dispersion of proposed values (10,000, 20,000, 50,000, 100,000, 200,000), the choice of "round” figures appears to be more appropriate for hygiene criteria (10^3, 10^4, 10^5, 10^6).
  - SRA (Sulphite-reducing bacteria growing in anaerobiosis): why adopt 20 rather than 10?
  - Coagulase positive Staphylococci: a limit of 100 cfu/g is generally adopted and the threshold of 1000 proposed for frozen raw, shelled prawns is not justified.

- *E. coli* / Thermotolerant coliforms

Thermotolerant coliforms growing at 44°C constitute a high performance hygiene criterion in many fisheries products, better than *Escherichia coli* which is detected more rarely in these products and therefore less effective in providing information. The choice of thermotolerant coliforms therefore appears to be more pertinent, although we propose to retain the *E. coli* criteria for cooked, shelled shellfish and molluscs and living shellfish, as this is adopted in Regulation (EC) No 2073/2005.

- TVBN (Total Volatile Basic Nitrogen) and TMA (trimethylamine)

The term “to be determined” appears in the federations’ proposals (Cf. Annex C.2) for fresh or deep-frozen raw fish fillets in the TVBN column. An interpretative approach to TVBN and TMA is proposed (CNERNA, 1996).

- *Salmonella*

The working group considered that *Salmonella* represents a safety criterion for products eaten raw and can be a hygiene indicator for products intended to be eaten cooked.
As the category involved is fish, *Salmonella* testing must not be performed systematically but must be considered depending on the origin of the product. The relevance of this research should be assessed by the operator in light of the specific situation of the foodstuff being tested.

- Pathogenic *Vibrio*

Pathogenic vibrio cannot be used as process hygiene criteria. These are micro-organisms carrying a risk to humans for which Regulation (EC) No 2073/2005 does not define a safety criterion but which can be subject to a withdrawal/recall procedure in terms of article 14 of Regulation (EC) No 178/2002. A revision

of Regulation (EC) No 2073/2005 could, however, be considered once an analytical method able to exclusively detect pathogenic strains is available.

Table 2 : Recommendations on hygiene criteria applicable to fishery products

Fisheries product	**PRODUCTION** (fresh leaving manufacturer or deep frozen)						**RETAIL SALES** (fresh, within use-by date)					
	MAF	Colif. 44	St. coag. +	SRA	*Salmonella* in 25 g	TVBN	MAF	Colif. 44	St. coag. +	SRA	*Salmonella* in 25g	TVBN
Fillets, other pieces and minced flesh of raw fish, raw molluscs (excluding live shellfish)	10^5	10	100		absent (1)	proposal (2)	10^6	(10)	(100)		absent (1)	
Live shellfish								*E. coli* : 230 NPP/100g of flesh and inter-valvar liquid				
Raw crustaceans: - whole	10^4	10		10	absent		10^6	(10)	-	(10)	(absent)	
- shelled or tails	10^5	10	100	10	absent		10^6	(10)	(100)	(10)	(absent)	
Whole cooked crustaceans	10^4	10	-	-	absent (3)		10^6	(10)	-	-	(absent)	
Shelled, cooked crustaceans and molluscs (4)	10^5	1 *E. coli*	100		*Absence (safety criterion)*		10^6	1 *E. coli*	100	10	(absent)	
Smoked and/or salted and/or marinated fish (5)	10^3	10	100				10^6	10	100			
Processed fish (cooked products): terrines, rillettes etc.	10^3	10	100				10^6	(10)	(100)			

(threshold value): to use if no supplier information
(1) testing for *Salmonella* limited only to products in which this is considered relevant

(2) TVBN for filets and other pieces of raw fish
TVBN criteria (mg nitrogen / 100 g)
Teleosteans:
- general situation: satisfactory:<20 - acceptable: 20 25 – unsatisfactory:>25
- other teleosteans (pollack, deepwater redfish, oily fish (eg : mackerel): satisfactory:<20 - acceptable: 20 to 30 - unsatisfactory:>30
Selachians: satisfactory:<30 - acceptable: 30 to 65 - unsatisfactory:>65
Cephalopods: satisfactory:<20 - acceptable: 20 to 25 - unsatisfactory:>25
These TVBN values are not applicable either to cooked products or those which have been processed or to fresh pre-packaged products.
For oily fish the TVBN levels provide information which must be considered against other assessment criteria.
TMA criteria: P =% TMA/TVBN : satisfactory:< 17% - acceptable: 17 to 40% - unsatisfactory:> 40%.
The TMA has no significance in selachians, crustaceans or cephalopods.

Commission **Regulation (EC) No 2074/2005** of 5 December 2005 states TVBN limits for some species:
- 25 mg nitrogen/100 g: *Sebastes spp*, *Helicolenus dactylopterus* (northern scorpion fish), *Sebastichthys capensis* (Cape redfish).
- 30 mg nitrogen/100 g: species belonging to the *Pleuronectidae* family (except for halibut) (Examples of *Pleuronectidae* : sole, lemon sole, flounder, plaice)
- 35 mg nitrogen/100 g: *Salmo salar* (atlantic Salmon); species belonging to the *Merlucciidae* family (hake) ; species belonging to the *Gadidae* family (cod, whiting, haddock...)
The product should be withdrawn from consumption if these values are exceeded. In drawing up specifications these withdrawal values cannot be used as quality references

(3) In the absolute, it is a safety criterion
(4) Criteria from Regulation (EC) No 2073/2005 shaded
(5) "Smoked and/or salted and/or marinated fish" GGPH criteria

D. Meat-based products and processed pork products

- **Meat-based products and processed pork products in the production stage** (Cf. Annex D.1)

Raw processed products should be distinguished from cooked processed products. Examination of the proposed criteria raises the following comments:

- Testing for *E. coli*, which is a genuine indicator of faecal contamination, appears to be more relevant than Enterobacteriaceaeor total or faecal coliforms. The parameter *E. coli* should therefore be preferred to the criterion Enterobacteriaceaeat 37°C.
- For the SRA per g, for the purposes of consistency, the same limit (10, 30 or 100 cfu/g) should be set for all food categories.
- It is recommended that a parameter coagulase positive Staphylococci (limit 100 cfu/g) be added for these products.

- **Raw processed pork products at the retailing stage** (Cf. Annex D.2)

There is no purpose in distinguishing between products depending on whether they are in supermarkets, community or commercial restaurant services. The parameters used must be the same for all situations. Examination of the proposed parameters raises the following comments:

- For raw processed meat ready to eat:
    - A limit of 100 cfu/g for coagulase positive Staphylococci is recommended in order to remain consistent with the other categories of foods;
    - SRA or *Cl. perfringens* (SRA testing should be preferred), the same limit (10, 30, or 100) should be set for all products.
- For raw processed meats intending to be cooked:
    - The proposed limit (1,000,000 cfu/g) for aerobic microorganisms at 30°C appears high;
    - Ratio of total flora to lactic flora: if the mesophilic flora count is high it must be ensured that this consists mostly of lactic flora;
    - The criterion “Enterobacteriaceae” is redundant with *E. coli*; the latter should be preferred.

- **Cooked processed pork products in the retail stage** (Cf. Annex D.3)

Categorising these products does not appear relevant. It is suggested that the 5 sub-categories of proposed products be grouped into a single category, to meet the following criteria:

- Mesophilic aerobic flora: the proposed limits (1 and 10,000 000 cfu/g) appear to be high. A limit of 300,000 cfu/g is recommended.
- Ratio of total flora to lactic flora (100): if the mesophilic flora count is high it must be ensured that this consists mostly of lactic flora.
- The criterion “Enterobacteriaceae” does not appear to be relevant when compared to *E. coli,* a genuine indicator of faecal contamination.
- Coagulase positive Staphylococci: a limit of 100 cfu/g is proposed to remain consistent with the other categories of foods.
- SRA or *Cl. perfringens* (SRA testing should be preferred): the same limit (10, 30 or 100) should be set for all other categories of foods.
- *Bacillus cereus*: a limit of 100 cfu/g is recommended in order to remain consistent with the other categories of foods;

It should be noted that testing for Salmonellae does not appear to be relevant when testing for *E. coli* and that measurement of core cooking temperature appears to be more useful.

Table 3 : Recommendations for hygiene criteria applicable to cooked processed pork meats in the retail stage

NAME	Scope	Plan	Aerobic microorganisms at 30°C per g	Lactic flora per g	Ratio of total flora to lactic flora	*E. coli* per g	Coagulase + Staphylococci per g	*Cl perf* or SRA per g	*Bacillus cereus* per g
Cooked processed pork products	Retail	n=1, c=0	300 000	yes	100	10	100	10, 30 or 100	*100*

E. Cooked dishes and various freshly produced products

Hygiene criteria have been proposed for:
- prepared foods and cooked dishes in the production stage
- cooked dishes in the retail stage
- sandwiches
- cold snacks
- various prepared foods, snacks

The term “Prepared food” does not define a foodstuff and should be avoided. For the purposes of this expertise, “prepared foods” have been likened to cooked dishes.
The proposed criteria applicable to cold snacks and various prepared foods have not been commented on. For these products, refer to the criteria applicable to the other categories of foods (cooked dishes, sandwiches, processed pork products, raw vegetable products, fisheries products, etc.).

- **Cooked dishes at the production stage** (Cf. Annex E.1)

Overpackaged products cooked in their packaging should be distinguished from other products within the cooked dishes category. The heat treatment used should be defined by a time/ temperature couple and the reference microorganism. It should also be stated whether the cooked dishes contain raw vegetables or fermented products in order to facilitate interpreting the mesophilic flora.

Examination of the proposed criteria raises the following comments:
- Testing for lactic flora could be useful depending on the product type.
- Testing for *E. coli*, which is a genuine indicator of faecal contamination, appears more relevant than Enterobacteriaceaeor the total or faecal coliforms. The criterion *E. coli* should therefore be used in preference.
- STEC *E. coli* are pathogenic microorganisms for which Regulation (EC) No 2073/2005 has not yet defined a safety criterion but can be subject to a withdrawal/recall procedure in terms of article 14 of Regulation (EC) No 178/2002. They cannot therefore be used as process hygiene criteria.
- *Bacillus cereus:* a limit of 100 cfu/g is recommended in order to remain consistent with the other categories of foods.

- **Cooked dishes at the retail stage** (Cf. Annex E.2)

It is suggested that the 5 sub-categories of products proposed be regrouped into a single category “cooked dishes sold hot or cooked on site” (the time/temperature couple should be stated) meeting the following criteria:
- Mesophilic aerobic flora: a limit of 300,000 cfu/g is recommended.
- Lactic flora should be tested if a product is vacuum-packed or contains cheese.
- Total flora to lactic flora (100): if the mesophilic flora count is high it must be ensured that this consists mostly of lactic flora.
- The criterion “Enterobacteriaceae” does not appear to be relevant compared to *E. coli* which is a genuine indicator of faecal contamination.

- Coagulase positive Staphylococci: a limit of 100 cfu/g is proposed to remain consistent with the other categories of foods.
- SRA or *Cl. Perfringens* (SRA should be used in preference): A limit (10, 30 or 100) should be set in order to remain consistent with the other categories of foods.
- *Bacillus cereus*: limit of 100 cfu/g is recommended in order to remain consistent with the other categories of foods*;*

It should be noted that testing for Salmonellae does not appear to be relevant when testing for *E. coli* and that measurement of core cooking temperature appears to be more useful.

Table 4: Recommendations for hygiene criteria applicable to cooked dishes in the retail stage

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per g	Lactic flora per g	Ratio of total flora to lactic flora	*E. coli* per g	Coagulase Staphylococci + per g	Cl. perf or SRA per g	*Bacillus cereus* per g
cooked dishes, sold hot or cooked on site	Retail	n=1, c=0	300,000	yes	100	10	100	10, 30 or 100	100

- **<u>Sandwiches in the retail stage</u>**(Cf. Annex E.3)

It is not appropriate to create 5 different categories of sandwiches. Sandwiches are complex products with different types of ingredients in variable proportions, which cannot be analysed individually:

- The main component is bread (raw or cooked) which is primarily rich in yeasts (and therefore in mesophilic flora).
- Raw vegetables are also present and contribute "total" or "faecal" coliforms.
- Processed pork meats or salmon can be sources of lactic flora.

As a result, testing for mesophilic and lactic flora does not appear to be appropriate in view of the interpretation difficulty which could arise. Only *E. coli* is relevant as an indicator of faecal contamination.
A single set of criteria is proposed regardless of the composition of the product.

Table 5: Recommendations for hygiene criteria applicable to sandwiches in the retail stage

NAME	Scope	Sampling plan	*E. coli* per g	Coagulase Staphylococci + per g	*SRA or Clostridium perfringens* per g
Sandwiches	Retail	n=1 c = 0	10	100	10, 30 or 100

F. Deep-frozen and frozen products (Production) (Cf. Annex F)

It is not appropriate to create specific criteria for deep-frozen or frozen products. The products must meet the same criteria whether they are frozen or refrigerated.
In the same manner as for cooked dishes, overpackaged products cooked in an airtight packaging should be distinguished from other products. The heat treatment used should be defined by a time/temperature couple and the reference microorganism.

- **<u>Frozen and deep-frozen products which have undergone a sterilisation treatment in the final packaging (eg. cooked dishes cooked in their packaging)</u>**

For these products, refer to the criteria applicable to fresh or refrigerated cooked dishes which have undergone a sterilisation treatment in their final packaging. (Cf. comments Table E.1). The criterion *Salmonella* does not appear to be relevant for these products.

- **<u>Frozen or deep-frozen products for which all of the ingredients are totally or partially cooked together or separately</u>**

For these products, refer to the criteria applicable to chilled cooked dishes cooked by heat treatment or ingredients cooked either together or separately by heat treatment. (Cf. comments Table E.1). Blanched or pre-cooked vegetables must be removed from this category.

- **Totally or partially cooked frozen or deep-frozen products**

Refer to the criteria applicable to chilled or refrigerated products with totally or partially cooked ingredients (Cf. comments Table E.1).

- **Aromatic herbs**

The criterion Enterobacteriaceaeat 37°C is redundant with *E. coli*. It is recommended that *E. coli* be used in preference with a limit of 10 cfu/g, particularly for flat-leaf parsley, dill and coriander which are the most sensitive products.

- **Deep-frozen vegetables**

The proposed criteria did not raise any comments from the group.

G. Pastries and desserts (retail) (Cf. Annex G)

The following terms must be defined: uncooked pastries, pastries and other desserts (all ingredients cooked), pastries containing custard, butter cream and derivatives or cooked pastries. Different criteria are proposed for supermarkets, community and commercial restaurant services without any actual justification.

It is suggested that a single series of criteria be used for pastries and other desserts, adding a yeasts and moulds criterion if Chantilly cream and raw vegetables are present:

- Mesophilic aerobic flora: a limit of 300,000 cfu/g is recommended.
- Ratio of total flora to lactic flora: If the mesophilic flora count is high it must be ensured that this consists mostly of lactic flora
- *E. coli*: a limit of 10 cfu/g is recommended
- Coagulase positive Staphylococci: a limit of 100 cfu/g is recommended
- SRA or *Cl. perfringens* (testing for SRA should be used in preference): a limit of 100 cfu/g is recommended.
- Yeasts and moulds (if Chantilly cream or raw vegetables present): a limit of 10,000 cfu/g is recommended.
- *Salmonella*: this is a safety criterion for some ovoproducts. For ovoproducts not concerned by this safety criterion, testing for *Salmonella* does not appear to be appropriate as a hygiene criterion since Salmonella, which may be introduced either by contamination by raw materials (eggs) or by handlers, may be controlled by HACCP, the effectiveness of which is confirmed by the criterion *E. coli.*

The group also recommends that the relevance of a criterion for *Bacillus cereus* be examined. According to the CNERNA, 1996 recommendations, if this criterion is relevant it could replace SRA.

Table 6: Recommendations for hygiene criteria applicable to pastries and desserts in the retail stage

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per g	Lactic flora per g	Ratio of total flora to lactic flora	*E. coli* per g	Coagulase Staphylococci + per g	*Clostridium perfringens* or SRA per g	Pastries and other desserts per g
Pastries and other desserts	Retail	n=1 c=0	300 000	yes	100	10	100	100	10 000 (Chantilly cream or raw vegetables)

For desserts containing fresh fruit and fresh fruit juices without Chantilly cream, it is recommended to refer to the criteria proposed for raw products and vegetables (Table I: Raw vegetable products – retail).

H. Dairy products and cheeses

- **Dairy products and cheeses in the production stage** (Cf. Annex H.1)

Analysis of the proposed criteria raises the following comments:
- UHT and sterilised drinking milks*:* it should be clarified that testing for aerobic microorganisms at 30°C takes place after incubating the milk at 30°C for 7 days.
- Pasteurised drinking milks: the criterion coliforms at 30°C appears in (repealed) Council Directive 92/46/EEC. This criterion is however redundant with the criterion "Enterobacteriacae" from Regulation (EC) No 2073/2005.
- Pasteurised butters: it is recommended that for coliforms at 30°C the threshold of 10 from the (repealed) Council Directive 92/46/EEC be used.
- Yoghurts and fermented milks: for the profession, the criterion "Enterobacteriaca" is currently being validated as a process hygiene indicator. CNERNA (1996) does not propose an "Enterobacteriaca" criterion for fresh dairy products of pH <4.5 as acidity results in these disappearing rapidly, unless they are tested for immediately after packaging and therefore before leaving the factory. It recommends replacing these with a criterion "Group D streptococci" (a suggestion which the working group does not itself adopt) and also that "yeasts and moulds" stability test be performed as this is the only real microbiological problem of deterioration raised by this type of product.
- Unpasteurised milk cheeses: it should be stated whether the limit of 100,000 cfu/g for *E. coli* (identical to M in Council Directive no. 92/46/EEC at the marketing stage) applies before or after refining.

The other proposed criteria do not raise any comments and are validated by the group.

- **Cheese in the retail stage** (Cf. Annex H.2)

A consensus between federations on the harmonised criteria between production and retailing would have been helpful, since criteria are proposed for pasteurised milk cheeses in the retail but not production stage.
Examination of the proposed criteria raises the following comments:
- For unpasteurised and heat treated milk cheeses it does not appear useful to set hygiene criteria for the retail stage. It would be difficult to distinguish endogenous flora from contamination flora.
- Testing for coagulase positive Staphylococci is useful for monitoring recontamination on cutting for refined or non-refined pasteurised milk cheeses if these are removed from their packagings and handled.
- The criterion *Salmonella* for refined or non-refined pasteurised milk cheeses does not appear to be appropriate. It is essential not to confuse product monitoring with monitoring of employees and premises which can be performed using the HACCP.

I. Raw vegetable products (Retail) (Cf. Annex I)

The term "salad" can describe very different categories of products. This should preferably be replaced by less generic and more specific terms such as leaf vegetables, fruit mixtures, etc.
Examination of the proposed criteria raises the following comments:
- At the supermarket Manufacturing stage, the microbiological limit proposed for the criterion *E. coli* is below the value in Regulation (EC) No 2073/2005 (m = 100, M = 1000). The proposed limits are also inconsistent between retail and community restaurant services (10 and 50 respectively). A difference in threshold value is not justified and it is therefore recommended that the threshold be harmonised for the criterion *E. coli* at 100 cfu/g.
- Testing for lactic flora is relevant for grated or finely sliced vegetables without dressing. Changes in flora, however, are not only due to the lactic flora. It would therefore be appropriate to propose an "aerobic microorganisms at 30°C" criterion for grated or finely sliced vegetables without dressing.
- The criteria proposed for fresh fruit salads at the fast food restaurant stage are not consistent with those proposed for retail sale. Why have the same requirement for lactic flora, a more stringent requirement for *E. coli* and less stringent requirement for yeasts and moulds at the same time? These criteria need to be harmonised.

The other criteria proposed do not raise any comments and are validated by the working group.

Conclusions on the relevance of the hygiene criteria proposed

The members of the working group would like to avoid the time taken to establish new references being prolonged unduly. They would prefer to temporarily accept sub-optimal criteria rather than allow the absence of criteria to continue. In examining the microbiological limits proposed by the professionals, the working group has only been able to consider in terms of orders of magnitude. In order to be able to consider absolute values the professional federations would need to clarify to what extent the proposed limits incorporate measurement uncertainty.

Accordingly, **subject to consideration of the comments made in this opinion**,

- the orders of magnitude of the hygiene criteria limits proposed for **fisheryproducts, dairy products, cheese and raw vegetable products** seem to be consistent with hygienic application of the processes considered;
- the orders of magnitude of the criteria limits for **frozen and deep-frozen products, meat-based products, processed pork products, cooked dishes, various freshly prepared products, pastries and desserts** could be used on a provisional basis.

Before ruling on the orders of magnitude of the criteria limits for **beef, poultry, rabbit and wild game products**, additional information described previously is requested from the federations concerned.

The following reservation applies in all cases: the criteria must be accompanied with a description of the sampling techniques. This point is important for all foods.

Afssa conclusion

Here are the elements that the French Food Safety Agency is able to provide the Directorate General for Food and the Directorate General for Competition Policy, Consumer Affairs and Fraud Control on the references applicable to foodstuffs as process hygiene criteria.

To help professionals establish process hygiene criteria in a well thought-through manner, Afssa has issued a self request to the “Microbiology” scientific panel to draw up "recommendations for establishing microbiological process hygiene criteria". These recommendations could be used by federations, trade unions and interprofessions in their discussions to establish microbiological criteria, all of which are convincingly in line with the "Hygiene Package". Guides to good practice for hygiene and for the application of HACCP principles may then be updated to take account of this work.

Key words; microbiological criteria; process hygiene criteria; Foodstuffs; Hygiene Package

The Director General

Pascale BRIAND

References

Regulatory texts and interpretation documents

- Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs
- European Commission Guidance Document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs

Afssa opinions on microbiological criteria

- AFSSA opinion of 18 January 2007 on the request to create reference documents on microbial flora which could be used as process hygiene criteria
- AFSSA opinion of 20 December 2005 on the draft order on microbiological criteria applicable to foodstuffs of animal origin repealing the ministerial order of 21 December 1979; and on the scientific interest of maintaining biological criteria for foodstuffs of plant origin and products intended for particular nutritional uses
- AFSSA opinion of 24 February 2006 on the draft order concerning the order on the repeal of national provisions on microbiological or health criteria applicable to products of animal origin and foodstuffs containing products of animal origin
- Afssa opinion of 25 June 2003 on the revision of the ministerial order of 21/12/1979 on microbiological criteria which certain animal foods or foods of animal origin must meet
- Afssa opinion of 14 March 2005 on microbiological criteria described in the draft Regulation on microbiological criteria applicable to foodstuffs SANCO 4198/2001 rev 14
- Afssa opinion of 25 March 2005 on the draft Community microbiological criteria for *Salmonella* in minced meat (SANCO 4198/2001 rev 14)

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Other scientific documents of interest

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Annex: Summary table of process hygiene criteria proposed by the professional federations

A. Meat and butchery products and raw meat products

1. Raw beef meat, minced meat, meat preparations, offal, blood for human consumption – Production

NAME	Scope	Sampling plan (1)	Aerobic microorganisms at 30°C per g	*Pseudomonas* or total flora per g (4)	Enterobacteriaceae at 37°C per g	*E. coli* per g	*Salmonella* in 25 g	Comments on the proposed criteria
Beef meat: mineral, ready to cut muscle	De-boning/trimming workshop End of manufacture	n=1 (change in results)	-	10 000	1 000	-	-	
Cut pieces of beef meat	Butchering workshop End of manufacture		-	10 000 (2)	1 000 (or E.coli)	100 (or Entero)	-	It is stated in the footer note that the criterion "*Pseudomonas"* should be interpreted as a function of the lactic flora. The lactic flora count, however, is not shown in this table.
Red beef offal at slaughterhouse (excluding head and tail meat) (3)	Slaughterhouse, end of cooling		-	100 000	1 000	-	-	
Red beef offal 1st processing stage bulk vacuum-packed (except head and tail meat) (3)	End of the manufacturing process		-	500 000	10 000	-	-	The factor of 5 between the limits for the criteria Enterobacteriaceae in red offal from the 1st and 2nd processing stage (10,000 and 50,000) must be justified. The differences in *E. coli* / Enterobacteriaceae at 37°C ratio between cut pieces of beef (100/ 1000) and 2nd processing stage offal (100/ 50000) must be justified. Second processing stage for red offal: It is stated in the footer note that the criterion "*Pseudomonas"* should be interpreted as a function of the lactic flora. The lactic flora count, however, is not shown in this table.
Red beef offal 2nd processing stage, separate pieces or consumer sales unit (except head and tail meat) (3)	End of the manufacturing process		-	500 000 (2)	50 000 (or E.coli)	100 (or Entero)	-	
Blood for human consumption	Collection (tank after bleeding)		1 000	-	100	-	Absence (5)	Testing for Salmonellae in 25 g is required if the criterion MAF 30°C or Enterobacteriaceaeis not met. What will the status of this criterion be?
Blood or blood product which has been processed and is intended for human consumption	End of manufacturing process		1 000 000	-	1 000	-	Absence (5)	

(1) Results monitored over time (preferably control charts), management of any deviations (detection and corrective actions). If no formal monitoring, the sampling plan used must be n=5, c=2.
(2) If only the criterion total flora is not met and the product was vacuum-packed or derived from a muscle under vacuum, this criterion should be interpreted as a function of the lactic flora.
(3) Sampling performed at the surface and at depth without cauterisation.
(4) It is for the operator to decide between the 2 flora to monitor production. The total flora should be counted at 25°C or 30°C depending on the company history and method used.
(5) Parameter only to be tested if the aerobic microorganisms at 30°C and/or Enterobacteraciae at 30°C criterion is not met.

2. Butchery meats, raw meat products - Retail

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per gram	Lactic flora per gram	Ratio of total flora to lactic flora	Pseudomonas per gram	*E. coli* per g	Coagulase + Staphylococci per gram	*Salmonella*	*E. coli* O157:H7 in 25 g	**Comments on the proposed criteria**
Pieces of meat or retail consumer packs, all species unpackaged or beneath a permeable sales film											
- obtained from exposed raw materials (including carcasses)	SM OS	n=1, c=0	-	-	-	To be determined	500	-	Absence in 10 g (1)	-	
- obtained from raw materials under vacuum or under protective atmosphere	SM OS / Butcher. EoM		To be determined	yes	100 (2)	-	500	-	Absence in 10 g (1)	-	A ratio of total flora to lactic flora of 100 appears high.
Meat preparations (marinated meats, meat skewers) intended to be eaten after cooking											
- obtained from exposed raw materials(including carcasses)	SM OS	n=1, c=0	-	-	-	To be determined	500 ***(4)***	-	Absence in 10 g	-	
- obtained from raw materials under vacuum or under protective atmosphere	SM OS		To be determined	yes	100 (2)	-	500 ***(4)***	-	Absence in 10 g	-	A ratio of total flora to lactic flora of 100 appears high.
Meat preparations intended to be eaten raw (carpaccio) or cooked (meat skewers, marinades…)	Butcher. EoM		-	-	-	-	***500 (4)***	-	-	-	
Minced meat intended to be eaten raw or cooked	Butcher. EoM		-	-	-	-	***50 (4)***	-	-	-	
Minced meats put on sale less than 24h after manufacture, tartare, carpaccio and other meats intended to be eaten raw	SM OS / Commercial rest.(1&2)		5 000 000 (3)	yes	100 (2)	-	50 ***(4)***	500	Absence in 25 g	Absent (5)	A ratio of total flora to lactic flora of 100 appears high compared to a total flora at 5,000,000 per gram.
Raw butchery offal	SM OS		5 000 000 (3)	-	-	-	5 000	-	Absent in 10 g (1)	-	

Grey box: Safety criterion from Regulation (EC) No 2073/2005:

(1) Optional: option available for some distributors (depending on commercial practices).
(2) Ratio to be used if the criterion aerobic microorganisms (= total flora) is not met.
(3) Temporary proposed criterion subject to validation in 12 months.
(4) Hygiene criterion for Regulation (EC) No 2073/2005 applicable only at the end of manufacture (and therefore if manufactured on site). If only thawing takes place in the warehouse this is a voluntary criterion for the professional
(5) Criteria adopted only by commercial restaurant services: this test can be performed on the raw material. It is recommended that the test for *E. coli* O157:H7 be supplemented by stx and eae gene testing.
SM = supermarkets
OS = On Sale (during their shelf-life)
EoM = End of Manufacture

B. Raw poultry, rabbit and game meat

1. Raw poultry and rabbit meat (fresh and frozen) – Production

NAME	Scope	Sampling plan (1)	Aerobic microorganisms at 30°C per gram	Lactic flora per gram	Ratio of total flora to lactic flora	coliforms at 30°C per gram	*E. coli* per gram	Coagulase + Staphylococci per gram	*Salmonella*	**Comments on the proposed criteria**
Poultry and rabbits, carcases and cut pieces with skin	End of manufacture in processing room	n=1 (change in results)	-	-	-	-	10 000	5 000	***Chicken and turkey absence in 25 g of neck skin***	The factor of 2 between the microbiological limits for the criteria *E. coli* and Coagulase + Staphylococci must be justified.
Cut pieces of raw rabbit without skin			-	-	-	-	1 000	5 000	-	The choice of the criterion *E. coli* for rabbit meat is debateable. *E. coli* is not a dominant part of the rabbit intestinal flora. Adopting such a high value for Coagulase + Staphylococci must be justified.
Cut pieces of raw poultry without skin			-	-	-	-	1 000		-	Coagulase + Staphylococci are not proposed whereas they are for cut rabbit pieces.
Poultry and rabbits: products involving stuffing, sausages, meat skewers, stuffings, minced meats, stuffed escalopes) and marinated products		***n=5, c=2***	-	-	-	-	***500***	-	Poultry: Absence in 10 g	The presence of these categories of products in the table is inappropriate. *E. coli* is tested in raw materials (whole animals and cut pieces) and coliforms at 30°C in finished products (meat and processed meat-based products). Harmonisation is required.
Poultry and rabbits: products containing cooked meat (cordon bleu, nuggets, roast wings)		n=1 (change in results)	300 000	-	-	1 000	-	-	-	
Processed poultry meat			300 000	yes	100 (2)	1 000	-	-	-	The ratio of total flora to lactic flora is high: it must be ensured that if the mesophilic flora count is high, that this consists mostly of lactic flora.
Raw poultry and rabbit offal			-	-	-	-	10 000	-	-	
Poultry and rabbits: minced meat and MSM, calcium content Ca <1000 ppm		***n=5, c=2***	***500 000***	-	-	-	***50***	-	Poultry: Absence in 10 g	The factor of 100 between the microbiological limits for the criteria *E. coli* in MSM with low calcium content and MSM with high calcium content must be justified. Testing for Salmonellae in 10 or 25 g should be used in preference.
Poultry and rabbits: MSM, Ca content Ca >1000 ppm		n=1 (change in results)	5 000 000	-	-	-	5 000	-	Absence in 1 g	

Safety criterion from Regulation (EC) No 2073/2005 ***Hygiene criterion for Regulation (EC) No 2073/2005***

(1) Results monitored over time (preferably control charts), management of any deviations (detection and corrective actions). If no formal monitoring, the sampling plan used must be n=5, c=2.

(2) Ratio to be used if aerobic microorganisms criterion is not met (= total flora)

2. Raw game meat – Production

NAME	Scope	Sampling plan (1)	Aerobic microorganisms at 30°C per gram	coliforms at 30°C per g	*E. coli* per g	Coagulase Staphylococci + per g	*Salmonella* in 25 g	**Comments on the proposed criteria**
Small wild game: whole animals and cut pieces with skin	End of manufacture in processing room	n=1 (change in results)	-	-	-	-	Absence	
Small farmed game: whole animals and cut pieces with skin from feathered game and cut pieces with skin from furred game			-	-	10 000	5 000	-	The proposed microbiological limit for coagulase + Staphylococci (5000) appears to be high and must be justified.

(1) Results monitored over time (preferably control charts), management of any deviations (detection and corrective actions). If no formal monitoring, the sampling plan used must be n=5, c=2.

3. Raw poultry and rabbit meat - Retail

NAME	Scope	Sampling plan	*Pseudomonas* per g	*E. coli* per g	Coagulase + Staphylococci per g	*Salmonella* in 10 g	**Comments on the proposed criteria**
Whole raw poultry and rabbits, raw cut pieces with skin, raw preparations of meat and meat based products WITH SKIN	SM OS	n=1, c=0	50 000 000 (3)	10 000	5 000	Absence (6)	The microbiological limit proposed for coagulase + Staphylococci (5000) appears to be high and must be justified.
Raw cut pieces without skin, raw preparations of meat and meat-based products WITHOUT SKIN	SM OS		50 000 000 (3)	1 000	1 000	Absence (6)	
Raw offal	SM OS		-	10 000	-	Absent	

(3) Temporary proposed criterion subject to validation in 12 months.
(6) Safety criterion from Regulation (EC) No 2073/2005 for meat preparations and poultry meat based products intended to be eaten cooked.

C. Fishery products

The comments and recommendations on the criteria applicable to fishery products are shown in the opinion.

1. Fishery products - Production

NAME	Scope	Sampling plan (1)	Aerobic microorganisms at 30°C per gram	Thermotolerant coliforms per gram	*E. coli* per gram	Coagulase + Staphylococci per gram	Sulph-reducing anaerobes per gram	Pathogenic *Vibrio* in 25 g	*Salmonella* in 25 g
Raw whole frozen/refrigerated shrimps	Processing room before cooking(RM)	n=1 (change in results)	10 000	10	-	-	20	Absent	Absent
Raw whole thawed shrimps	End of manufacture in processing room		10 000	-	1	-	-	-	Absent
Raw shrimps	Processing room before cooking(RM)		200 000	100	-	1 000	20	Absent	Absent
Cooked whole frozen/refrigerated shrimps	End of manufacture in processing room		10 000	-	1	-	-	-	Absent
Cooked shelled frozen/refrigerated shrimps	End of manufacture in processing room		50 000	-	***1***	***100***	-	-	Absent
Raw frozen shrimp tails	Processing room before cooking(RM)		100 000	50	-	1 000	20	Absent	Absent
Cooked frozen/refrigerated shrimp tails	End of manufacture in processing room		50 000	-	1	100	-	-	Absent
Whole frozen/refrigerated raw prawns and langoustines	Processing room before cooking(RM)		20 000	10	-	-	20	Absent	Absent
Whole frozen/refrigerated cooked prawns and langoustines	End of manufacture in processing room		10 000	-	1	-	-	-	Absent
Safety criterion from Regulation (EC) No 2073/2005		***Hygiene criterion for Regulation (EC) No 2073/2005***							

(1) Results monitored over time (preferably control charts), management of any deviations (detection and corrective actions). If no formal monitoring, the sampling plan used must be n=5, c=2.

RM raw material

2. Fishery products and shellfish – Retail

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per gram	Lactic flora per gram	Ratio of total flora to lactic flora	Enterobacteriaceaeat 30°C per gram	*E. coli* per gram	coagulase + Staphylococci per gram	*Clostridium perfringens* per gram	*Salmonella* in 25 g	TVBN in mg/100 g
Raw, fresh or deep-frozen cephalopods	SM OS	n=1, c=0	-	-	-	-	10	100	-	-	-
Filets and other pieces of raw, fresh or frozen fish	SM OS		-	-	-	-	10	100	-	-	To be determined
Raw preparations containing minced mince fillets	SM OS		-	-	-	-	50	100	-	-	-
Raw prawns, shrimps (put on sale)	SM OS		To be determined	-	-	-	10	100	-	-	-
Raw de-shelled scallops	SM OS		-	-	-	-	10	100	-	-	-
Cooked non deheaded or deheaded crustaceans, shellfish and molluscs	SM OS Commercial rest.(1&2)		1 000 000	-	-	-	10	-	10 (7)	Absence	-
Cooked deheaded molluscs and shellfish cooked on site including shrimps (ready to eat)	SM Manufacture		5 000 000	-	-	-	***1***	***100***	-	Absence	-
Molluscs and crustaceans received deheaded and cooked, including shrimps (ready to eat)	SM OS		5 000 000	-	-	-	10	100	-	Absence	-
Crustaceans, shellfish and molluscs, cooked, de-shelled or deheaded	Commercial rest.(1&2)		1 000 000	-	-	-	10	100	10 (7)	Absence	-
Living shellfish	SM OS / Commercial rest.(1&2)		-	-	-	-	1 or 230 NPP/100g	-	-	Absence	-
Smoked Salmon, trout, tuna, eel, smoked halibut	SM OS		5 000 000 (3)	yes	100 (2)	-	10	100	-	-	-
Other smoked fish such as sprats, mackerel, herring, haddock	SM OS		50 000 000 (3)	yes	100 (2)	-	10	100	-	-	-
Smoked fish and marinated fish	Pork products caterer		1 000 000 (9)	yes (9)	100 (2) (9)	1 000	10 (8)	-	-	-	-

Safety criterion from Regulation (EC) No 2073/2005 ***Hygiene criterion for Regulation (EC) No 2073/2005***

(2) Ratio to be used if the criterion aerobic microorganisms (= total flora) is not met.
(3) Temporary proposed criterion subject to validation in 12 months. (7) Criterion to be used if cooked on site. Analysis to be performed as a priority on raw material if cooked at the supplier. (8) Parameter only to be tested if the criterion Enterobacteraciae at 30°C is not met (9) Search carried out if packaged under vacuum or under protective atmosphere.

D. Meat-based products and processed pork products

1. Meat products, processed pork products – Production

NAME	Scope	Sampling plan (1)	Aerobic microorganisms at 30°C per g	Lactic flora per g	Ratio of total flora to lactic flora	Enterobacteriaceae at 37°C per g	*E. coli* per g	SRA at 46°C per g	Comments on the proposed criteria
Product containing raw meat, sausages or sausage meat	End of manufacture in processing room	n=1 (change in results)	-	-	-	10 000 (or E.coli)	500 (or Entero)	-	These products should be grouped into a single category "Raw processed meat products" Testing for Enterobacteriaceae should be supplemented by *E. Coli* (*E. coli* <500) for hygiene control. It is recommended that a criterion be added for coagulase positive Staphylococci (<100) SRA per g: The same (10, 30 or 100) should be set for all of the food categories. Salted meat products: the merits of testing for aerobic microorganisms at 30°C (AM 30°C) is debatable. Ratio of total flora/lactic flora: It should be ensured that if the mesophilic flora count is high that this consists mostly of lactic flora.
Raw processed pork products intended to be cooked such as sausages for cooking			-	-	-	10 000	-	-	
Ready to eat Raw processed pork productse.g. dry sausage			-	-	-	1 000	-	-	
Salt meat products intended to be eaten cooked			To be determined	yes	100 (2)	10 000	-	-	
Ready to eat Salt meat products			To be determined	yes	100 (2)	1 000	-	-	
Products containing cooked meats			-	-	-	50 (3)	-	30 (SRA or *C. perf.*)	The use of testing for AM 30°C is debateable. The criterion *E. coli (<10)* appears to be more relevant than the criterion Enterobacteriaceaeat 37°C. SRA per g: The same (10, 30 or 100) should be set for all of the food categories. It is recommended that a criterion be added for coagulase positive Staphylococci (<100).
Cooked processed pork products such as tripe and tripe related products ("andouillette"), blood pudding, jelly, feet, rillettes			-	-	-	50 (3)	-	30 (4)	
Processed meats: cooked meat pieces, pâtés which are not handled after cooking			To be determined (at 20°C ?)	-	-	-	-	-	
Processed meat: cooked meat pieces handled after cooking			To be determined	yes	100 (2)	50 (3)	-	-	
Processed meats: pâtés handled after cooking, jellied products, sausages and cooked sausages			To be determined	yes	100 (2)	50 (3)	-	30 (4)	

(1) Results monitored over time (preferably control charts), management of any deviations (detection and corrective actions). If no formal monitoring, the sampling plan used must be n=5, c=2.

(2) Criterion to be determined depending on the company history, ratio to be applied if the criterion aerobic microorganisms (= total flora) is not met, can validate the procedures.

(3) Criterion not relevant for cooked products in their packaging if the heat treatment is validated (Vp > 40).

(4) Subject to validation for cooked poultry products.

2. Raw processed pork products - Retail

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per g	Lactic flora per g	Ratio of total flora to lactic flora	*Pseudomonas* per g	*Brochothrix* per g	Enterobacteriaceae at 30°C per g	*E. coli* per g	Coagulase + Staphylococci per g	*Clostridium perfringens* per g	*Salmonella*	Comments on the proposed criteria
Raw processed meats and ready to eat salt meat products (dry sausage, dry ham…..)	SM OS	n=1, c=0	-	-	-	-	-	-	10	500	-	Absence in 25 g (10)	It is not appropriate to distinguish between products depending on whether they are sold in supermarkets or community restaurant services. The same criteria must be used in all cases. Coagulase positive Staphylococci : a limit of 100 is recommended in order to be consistent with the other food categories. Cl. perf or SRA per g : The same limit (10, 30 or 100) should be set for all food categories.
	Community Rest.		-	-	-	-	-	-	10	500	10	Absence in 25 g (10)	
Raw processed meats intended to be eaten raw or starters containing raw processed meats	Commercial rest. (1&2)		-	-	-	-	-	-	10	500	50 (7c)	Absence in 25 g (10)	
Raw processed minced meats to be consumed after cooking (sausages, sausage meat)	SM OS		-	-	-	To be determined	-	-	***500 (4)***	500	-	Absence in 10 g (11)	Difference between "to consume after cooking" and "consume cooked"? A limit of 1,000,000 for AM 30°C appears high. Ratio of total flora/lactic flora: If the mesophilic flora count is high it must be ensured that this consists mostly of lactic flora. The criteria *Pseudomonas* and *Brochothrix* do not appear relevant. The criterion Enterobacteriaceae at 37°C is redundant with *E. coli*. *E. coli* should be used in preference.
	Pork products caterer		1 000 000	yes (9b)	100 (2) (9b)	-	To be determined	10 000	***500 (4)***	-	-	Absence in 10 g (11)	
Raw processed meats to be consumed cooked (lardons, breast, loins)	Pork products caterer		1 000 000	yes (9)	100 (2) (9)	-	To be determined	10 000	***500 (4)***	-	-	Absence in 10 g (11)	

Safety criterion from Regulation (EC) No 2073/2005 (1) Optional: option available for some distributors (depending on commercial practices). (2) Ratio to be used if the criterion aerobic microorganisms (= total flora) is not met. ***(4) Hygiene criterion for Regulation (EC) No 2073/2005 applicable only at the end of manufacture (and therefore if manufactured on site). If only thawing takes place in the warehouse this is a voluntary criterion for the professional***. (7c) Criterion could be reconsidered as 10 per g as in community restaurant services subject to validation in 12 months (9) Test performed if packaged under vacuum or under protective atmosphere. (9b) Search conducted if packaged under vacuum or under protective atmosphere, with shelf life more than 7 days. (10) Safety criterion from Regulation (EC) No 2073/2005 to be applied only for dry sausage type products. (11) Safety criterion from Regulation (EC) No 2073/2005 for meat preparations.

3. Cooked processed meat products - Retail

The comments and recommendations on criteria applicable to cooked processed pork products at the retail stage are shown in the opinion

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per gram	Lactic flora per gram	Ratio of total flora to lactic flora	Enterobacteriaceae at 30°C per gram	*E. coli* per gram	Coagulase + Staphylococci per gram	*Clostridium perfringens* per gram	*Bacillus cereus* per gram	*Salmonella* in 25 g
Cooked processed meats	SM OS	n=1, c=0	10 000 000 (3)	yes	100 (2)	-	10	100	-	-	Absent
	Community rest.		1 000 000 (3)	yes	100 (2)	-	10	100	10	-	Absent (13)
Cooked processed meats or starters containing cooked processed meats or cooked meats	Commercial rest.(1&2)		1 000 000	yes	100 (2)	-	10	100	30 (7)	100 (12)	Absent
Products containing cooked meats (cooked pressed beef)	Butcher. OS		-	-	-	1 000	10 (8)	-	100 (*C. perf.* or SRA)	-	-
Ready to eat cooked processed meats (ham, pâtés, galantines)	Pork products caterer		1 000 000	yes (9)	100 (2) (9)	1 000	10 (8)	-	-	100 (12)	-
Manufacturer's "in house" jellied products	Pork products caterer		1 000	-	-	-	-	-	-	-	-

(2) Ratio to be used if the criterion aerobic microorganisms (= total flora) is not met.
(3) Temporary proposed criterion subject to validation in 12 months.
(7) Criterion to be used if cooked on site. Test to be performed in preference on the raw material if cooking is performed at the supplier's premises.
(8) Parameter to be tested only if the criterion Enterobacteraciae at 30°C is not met.
(9) Test to be performed if packaged under vacuum or under protective atmosphere
(12) Criterion to be used only for products containing starchy ingredients, such as quenelles, white pudding, pasties...or containing raw vegetables (Fast food: if foodstuff is cooked and eaten at different times).
(13) Criterion to be used only for products containing head or foot.

E. Cooked dishes and assorted prepared products (sandwiches, cold snacks, etc.)

1. cooked dishes – Production

NAME	Scope	Sampling plan (1)	Aerobic microorganisms at 30°C per g (2)	Enterobacteriaceae at 37°C per g (3)	Coagulase + Staphylococci per g	Sulph-reducing anaerobes. 46°C per gram	*Bacillus cereus* per g	*E. coli* STEC in 25 g	*Salmonella* in 25 g	**Comments on the proposed criteria**
Fresh or refrigerated delicatessen products which have undergone sterilisation treatment in final packaging (eg. dishes cooked under vacuum)	End of the manufacturing process	n=1 (change in results)	-	-	-	100 (SRA or *C. perf.*)	1 000	-	-	For heat treatment, the time/temperature couple and reference microorganism should be stated. *Bacillus cereus* per g: a limit of 100 is recommended in order to remain consistent with other categories of foods.
Fresh or refrigerated delicatessen products: cooked by heat treatment (e.g. quenelles, fresh pasta) or ingredients cooked together or separately by heat treatment (e.g. quiches, savoury tarts, spring rolls, sandwiches...)			100	10 (Enterob. or Total colis.)	Absence (4)	100 (SRA or *C. perf.*)	1 000	-	Absence	It would be sensible to remove raw products from this category. Testing for lactic flora may be useful depending on product type. The criterion *E. coli* (<10) appears to be more relevant that the criterion Enterobacteriaceae at 37°C. Coagulase positive Staphylococci: a limit of 100 is recommended in order to remain consistent with the other categories of foods. *Bacillus cereus* per g: a limit of 100 is recommended in order to remain consistent with mesophilic aerobic flora and the other categories of foods.
Fresh or refrigerated delicatessen products with totally or partially raw ingredients (e.g. tart pastry, pizzas, prepared salads, , sandwiches...)										It is inappropriate to have different criteria depending on whether or not cooked at consumer's home. A limit of 1000 for the AM 30°C appears inapplicable. The criterion *E. coli (<10)* appears to be more relevant than the criterion Enterobacteriaceae at 37°C. *Bacillus cereus* per g: a limit of 100 is recommended in order to remain consistent with the other categories of foods. *E. coli* STEC is not relevant as a process hygiene criterion.
- cooking by consumer is mandatory								-		
- cooking by consumer is not mandatory			1 000	100 (Enterob. or Total colis.)	100	100 (SRA or *C. perf.*)	1 000	Absence	Absence	

(1) Results monitored over time (preferably control charts), management of any deviations (detection and corrective actions). If no formal monitoring, the sampling plan used must be n=5, c=2.
(2) Criterion to be interpreted depending on the composition of the products and their lactic flora content. (3) Criterion to be used if the establishment HACCP plan reveals that these microorganisms are indicative of failures of raw materials or processes (4) Cooking of all ingredients combined with observance of GHPGs must result in absent Staphylococci, although problem with analytical method to use.

2. Cooked dishes – Retail

The comments and recommendations on the criteria applicable to cooked dishes in the retail stage are shown in the opinion

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per gram	Lactic flora per gram	Ratio of total flora to lactic flora	Enterobacteriaceae at 30°C per g	*E. coli* per g	Coagulase + Staphylococci per g	*Clostridium perfringens* per g	*Bacillus cereus* per g	*Salmonella* in 25 g
Delicatessen products sold hot or cooked on site (not derived from raw materials under vacuum or which have reached a core temperature of 70°C)	SM Manufacture	n=1, c=0	300 000	-	-	1 000	10	100	30 (14)	100 (12b)	Absence
	SM OS		3 000 000	-	-	-	10	100	30 (14)	100 (12b)	Absence
Delicatessen products sold hot or cooked on site (derived from raw materials under vacuum or which have reached a core temperature of 70°C)	SM Manufacture	n=1, c=0	300 000	yes	100 (2)	-	10	100	30 (14)	100 (12b)	Absence
	SM OS		3 000 000	yes	100 (2)	-	10	100	30 (14)	100 (12b)	Absence
Cooked dishes, sauces											
- not handled after cooking	Community Rest.	n=1, c=0	300 000	-	-	-	10	-	30 (14)	100 (12)	-
- handled after cooking (e.g. sliced, cooled, packaged)			300 000	-	-	-	10	100	30 (14)	100 (12)	-
Cooked dishes derived from eggs in shells (omelettes, fried eggs)	Community Rest.	n=1, c=0	300 000	-	-	-	10	-	-	-	Absence
Cooked dishes, sauces, served hot or cold											
- without cheese or uncooked ingredient	Commercial rest.(1&2) / Fast food	n=1, c=0	3 000 000	-	-	-	10	100	30 (14)	100 (12)	Absence
- containing an uncooked ingredient, e.g. grated cheese)			3 000 000	yes	100 (2)	-	10	100	30 (14)	100 (12)	Absence
Cooked dishes											
- containing meat or fish (general case)	Pork products caterer	n=1, c=0	-	-	-	1 000	10 (8)	-	30	-	-
- containing meat or fish (cooked under vacuum or packaged under vacuum)			1 000 000	yes	100 (2)	1 000	10 (8)	-	30 (7b)	-	-
- with products rich in starch (vol au vents, pasta bakes, rice, mashed potato, etc.)			-	-	-	1 000	10 (8)	-	30	100	-

(2) Ratio to be used if the criterion aerobic microorganisms (= total flora) is not met. (7b) SRA not tested if shelf life less than 21 days. (8) Parameter only to be tested if the criterion Enterobacteraciae at 30°C is not met. (12) Criteria to be used only for products containing starchy ingredients, such as quenelles, white pudding, pork pies...or containing raw vegetables (Fast food: if foodstuff cooked and

eaten at different times). (12b) Criterion to be used only for products rich in starch, containing starchy ingredients (semolina, rice, pasta, potatoes, lentils, etc.) (14) Criterion to be used only for products containing meat productss and foods of animal origin.

3. Sandwiches - Retail

The comments and the recommendations on the criteria applicable to sandwiches at the retail stage are shown in the opinion

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per gram	Lactic flora per gram	Ratio of total flora to lactic flora	*E. coli* per gram	coagulase +Staphylococci per gram	*Clostridium perfringens* per gram	*Salmonella* in 25 g
Sandwiches and paninis (with or without raw vegetables)									
- not containing raw processed pork or unpasteurised milk cheese	Commercial rest.(1&2) / Fast food	n=1, c=0	1 000 000 (3)	yes	100 (2)	10	100	10 (15)	Absent
- with raw processed pork, no unpasteurised milk cheese			-	-	-	10	500	10 (15)	Absent
- with unpasteurised milk cheese			-	-	-	10 000	10 000	10 (15)	Absent
Hot sandwiches, Burger type	Fast food	n=1, c=0	To be determined	yes ?	100 ? (2)	10	100	-	Absent
Hot sandwiches, Meat skewer type	Fast food		To be determined	yes ?	100 ? (2)	10	100	30	Absent

(2) Ratio to be used if the criterion aerobic microorganisms (= total flora) is not met.
(3) Temporary proposed criterion subject to validation in 12 months.
(15) This analysis can be performed on the raw material if the at risk ingredient is cooked at the supplier's premises.

4. Cold entrée – Retail

The proposed criteria applicable to cold snacks and various delicatessen products (Table 5) are not discussed. Refer to the criteria applicable to other categories of foods (cooked dishes, sandwiches, processed pork products, raw vegetable products, fisheries products, etc.)

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per gram	Lactic flora per gram	Ratio of total flora to lactic flora	Enterobacteriaceae at 30°C per gram	*E. coli* per gram	*Clostridium perfringens* per gram	coagulase + Staphylococci per gram	*Bacillus cereus* per gram	*Salmonella* in 25 g
Cold entrée											
- with raw processed pork to be eaten in native state	Community Rest.	n=1, c=0	1 000 000 (3)	yes	100 (2)	-	10	10	500	100 (12 & 12b)	-
- with meat products other than raw processed pork to be eaten in native state			1 000 000 (3)	yes	100 (2)	-	10	10	100	100 (12 & 12b)	-
- without meat products			1 000 000 (3)	yes	100 (2)	-	10	-	100	100 (12 & 12b)	-
Cold entrée											
- with animal foodstuffs or foods of animal origin and/or raw vegetables, without raw vegetables	Commercial rest.(1&2)	n=1, c=0	1 000 000 (3)	yes	100 (2)	-	10	10 (14b)	100	100 (12b)	Absence
- with raw vegetables	Commercial rest.2		50 000 000 (3)	-	-	-	10	10 (14b)	100	100 (12b)	Absence
- with raw seafood products (fish tartare, marinated fish ….) and with raw vegetables			50 000 000 (3)	-	-	-	100	10 (14b)	100	100 (12b)	Absence
- with seafood products (fish tartare, marinated fish ….) and without raw vegetables			1 000 000 (3)	yes	100 (2)	-	100	10 (14b)	100	100 (12b)	Absence
Preparation (salads etc) with raw vegetables and animal foods (cheese type)	Commercial rest.1 /. Fast food	n=1, c=0	10 000 000 (3)	yes	100 (2)	-	10	-	100	100 (12 & 12b)	Absence
Hors d'œuvre containing meat or fish	Pork products caterer		-	-	-	1 000	10 (8)	-	100	100 (12b)	Absence

(3) Temporary proposed criterion subject to validation in 12 months.
(8) Parameter to be tested only if the criterion Enterobacteriaceaeat 30°C is not met.
(12) Criteria to be used only for products containing starchy ingredients, such as quenelles, white pudding, pasties...or containing raw vegetables (Fast food: if foodstuff is cooked and eaten at different times).
(12b) Criterion to be used only for products rich in starch, containing starchy ingredients (Semolina, rice, pasta, potatoes, lentils, etc).
(14b) Criterion to be used only if food contains cooked meat products, egg products or seafood products (Fast food: if food contains meat products or seafood products but is cooked for later consumption)

5. Various prepared products, snacks… - Retail

NAME	Scope	Plan	Aerobic microorganisms at 30°C per gram	Lactic flora per gram	Ratio of total flora to lactic flora	Enterobacteriaceae at 30°C per gram	*E. coli* per gram	coagulase + Staphylococci per gram	*Clostridium perfringens* per gram	*Bacillus cereus* per gram	*E. coli* O157:H7 in 25 g	*Salmonella* in 25 g
Delicatessen products sold cold	SM Manufacture	n=1, c=0	1 000 000	yes	100 (2)	-	10	100	-	100 (12c)	-	Absence
	SM OS		10 000 000	yes	100 (2)	-	10	100	-	100 (12c)	-	Absence
Delicatessen products sold cold with uncooked unpasteurised milk cheese	SM OS		-	-	-	-	10 000	10 000	-	100 (12c)	-	Absence
Processed fish (example: fish terrine, fish rillettes)	SM OS		10 000 000 (3)	yes	100 (2)	-	10	100	-	-	-	Absence (1)
	Pork products caterer		1 000 000	yes (9b)	100 (2) (9b)	1 000	10 (8)	-	-	-	-	-
Cooked hot snacks, pork products with pastry served hot or cold (finger foods, quiches, pizza, savoury tarts, pancakes, etc)												
- without uncooked ingredient	Commercial rest.(1&2) / Fast food		100 000	-	-	-	10	100	30 (14b)	100 (12)	-	Absence
- with uncooked ingredient (e.g. grated cheese)			1 000 000	yes	100 (2)	-	10	100	30 (14b)	100 (12)	-	Absence
Ready to eat pork products with pastry (finger foods, quiches…)	Pork products caterer		1 000 000	-	-	1 000	10 (8)	-	-	100 (12)	-	-
Minced meat not cooked to core	. Community Rest.		500 000	-	-	-	50	-	-	-	Absent (5b)	Absence
Part cooked or seared minced meat	Commercial rest.(1&2)		3 000 000	-	-	-	50	100	30	-	Absent (5b)	Absence

(1) Optional: possible option for some distributors (depending on commercial practices).
(2) Ratio to be used if the criterion aerobic microorganisms (= total flora) is not met.
(3) Temporary proposed criterion subject to validation in 12 months.
(5b) This analysis can be performed on the raw material. It is recommended that the test for *E. coli* O157:H7 be supplemented by testing for stx and eae genes. (8) Parameter to be tested only if the criterion Enterobacteraciae at 30°C is not met. (9b) Search conducted if packaged under vacuum or under protective atmosphere with a shelf life of more than 7 days. (12) Criterion to be used only for products containing starchy ingredients, such as quenelles, white pudding, pork pies...or containing raw vegetables (Fast food: if foodstuff cooked and eaten at different times). (12c) Criterion to be used only for products rich in starch containing starchy ingredients excluding bread (semolina, rice, pasta, potatoes, lentils, etc) (14b) Criterion to be used only if food contains cooked meat products, egg products or seafood products (Fast food : if food contains meat products or seafood products but cooked for later consumption).

F. Deep-frozen and frozen products – Production

NAME	Scope	Sampling plan (1)	Aerobic microorganisms at 30°C per g	Enterobacteriaceaeat 37°C per gram	*E. coli* per g	Coagulase + Staphylococci per g	Sulph-reducing anaerobes. per g	*Bacillus cereus* per g	*Salmonella* in 25 g	Comments on the proposed criteria
Frozen and deep-frozen products which have undergone sterilising treatment in the final package (e.g. dishes cooked in their packaging)	End of the manufacturing processing	n=1 (change in results)	-	-	-	-	100	-	Absence	For these products, refer to the criteria applicable to chilled or refrigerated cooked dishes which have undergone sterilising treatment in the final packaging. This treatment must be performed in an airtight package. The criterion *Salmonella* does not appear to be relevant for these products (not proposed for fresh products).
Frozen or deep-frozen products in which all of the ingredients are totally or partially cooked either together or separately, e.g. quiches, savoury tarts, waffles, cooked tart bases, cooked tarts, cooked bases and garnishes, blanched or pre-cooked vegetables			To be determined by each professional	100	10	100	100	-	Absence	For these products, refer to the criteria applicable to cooked dishes. Blanched or pre-cooked vegetables must be removed from this category.
Totally or partially raw frozen or deep-frozen products, e.g. lasagnes, puff pastries, portions of fish in sauce (raw fish, cooked sauce), stuffed vegetables (raw vegetables, cooked or raw stuffing, raw fruit tarts, sandwiches, pizzas…) **(excluding aromatic herbs and vegetables)**			To be determined by each professional	10 000	1 000	100	100	-	Absence	For these products, refer to the criteria applicable to cooked dishes.
Aromatic herbs			To be determined by each professional	50 000	1 000	100	100	-	Absence	The criterion Enterobacteriaceae at 37°C is redundant with *E. coli*. *E. coli* should be preferred (limit 10).
Deep-frozen vegetables										
- raw			1 000 000	-	100 ***(2)***	-	-	1 000 (3)	Absence (1)	
- blanched			500 000			-				
- other (processed)			1 000 000			100				

(1) Results monitored over time (preferably control charts), management of any deviations (detection and corrective actions). If no formal monitoring, the sampling plan used must be n=5, c=2. (2) Criteria from Regulation (EC) No 2073/2005 for pre-cut vegetables (ready to eat). (3) Criterion to use for validation or verification but not for monitoring

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G. Pastries, desserts – Retail

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per g	Lactic flora per g	Ratio of total flora to lactic flora	Enterobacteriaceae at 30°C per g	*E. coli* per g	Coagulase + Staphylococci per g	*Clostridium perfringens* per g	Yeasts and moulds per g	*Salmonella* in 25 g	**Comments on the proposed criteria**
Uncooked pastries	SM Manufacture	n=1, c=0	300 000	-	-	-	1	100	-	-	Absence(16)	This category should be defined and examples given.
	SM OS		3 000 000	-	-	-	10	100	-	-	Absence (16)	AM 30°C: It is not appropriate to have different criteria between sales and Community restaurant services
	Community restaurant		300 000	-	-	-	10	100	-	-	Absence (16)	
Pastries and other desserts (all ingredients cooked)	SM Manufacture		30 000	-	-	-	1	100	-	-	-	This category should be defined and examples given.
	SM OS / Fast food		300 000	-	-	-	10	100	-	-	-	
Pastries containing custard, butter cream and derivatives or cooked pastries	Community restaurant		300 000	-	-	-	10	100	-	-	-	This category should be defined and examples given.
Pastries and other desserts												It would be sensible to use a single set of criteria for pastries and other desserts adding a criterion yeasts and moulds if Chantilly cream or raw vegetables present
- without Chantilly cream	Commercial rest.(1&2)		300 000	-	-	-	10	100	10 (14c)	-	Absence	
- with Chantilly cream			3 000 000	yes	100 (2)	-	100	100	10 (14c)	-	Absence	
Desserts containing fresh fruit and fresh fruit juice												
- without Chantilly cream	Commercial rest.(1&2)		-	10 000	-	-	10	-	-	10 000	Absence	Refer to the criteria applicable to raw fruits and vegetables.
- with Chantilly cream			3 000 000	yes	100 (2)	-	100	-	-	10 000	Absence	
Frozen desserts such as Milk shakes, sundaes	Fast food		600 000	-	-	3 000	10	100	-	-	-	

(2) Ratio to be used if the criterion aerobic microorganisms (= total flora) is not met.
(14c) Criterion to be used only if food contains dried fruits (hazelnuts, almonds), red fruits, rice or semolina based desserts cooked with milk.
(16) Safety criterion from Regulation (EC) No 2073/2005 for ready to eat products containing raw eggs.

H. Dairy products and cheeses

1. Dairy products Cheeses – Production

NAME	Scope	Sampling plan (1)	Aerobic microorganisms at 30°C per g	Enterobacteriaceae at 37°C per g	coliforms at 30 °C per g	*E. coli* per g	Coagulase + Staphylococci per g	*Salmonella* in 25 g	**Comments on the proposed criteria**
Sterilised and UHT milk	End of the manufacturing process	n=1 (change in results)	10 cfu/0.1ml	-	-	-	-	-	Clarify "after incubation for 7days at 30°C"
Pasteurised milk			1 000	***1 /ml***	1 /ml	-	-	-	The criterion coliforms at 30°C is redundant with the criterion "Enterobacteraciae" from Regulation 2073/2005.
Pasteurised creams			-	-	10	-	-	-	
Pasteurised butters			-	-	100	-	-	-	The limit of 10 from Directive 92/46/EEC repealed is recommended.
Concentrated butters / anhydrous milk fat			-	-	10	-	-	-	
Yoghurts and fermented milks			-	100 (2) (or Total coliforms.)	10 (or Enterob.)	-	-	-	The criterion Enterobacteraciae is not relevant for highly acid yoghurts pH<4.5.
Fresh dairy desserts			-	10 (2) (or Total coliforms.)	10 (or Enterob.)	-	-	-	
raw milk cheeses			-	-	-	100 000	***10 000*** (3)	Absence	State whether the limit for *E. coli* applies before or after refining

Safety criterion from Regulation (EC) No 2073/2005 ***Hygiene criterion for Regulation (EC) No 2073/2005***

(1) Results monitored over time (preferably control charts), management of any deviations (detection and corrective actions). If no formal monitoring, the sampling plan used must be n=5, c=2.

(2) Use the criteria coliforms pending validation of the criterion Enterobacteraciae.

(3) Testing for Staphylococcal Enterotoxins at and above 100,000 Staph per g.

2. Cheeses – Retail

NAME	Scope	Sampling plan	*E. coli* per gram	Coagulase + Staphylococci per gram	*Salmonella* in 25 g	**Comments on the proposed criteria**
raw milk cheeses	SM OS / Commercial rest.(1&2)	n=1, c=0	10 000	10 000 (17)	Absence	It does not appear useful to set hygiene criteria at this stage.
	Creamery/cheese dairy		10 000	-	Absence	
Refined cheeses made from pasteurised milk	SM OS / Commercial rest.(1&2)		100	100 (17)	Absence (18)	The criterion CPS is useful if the cheeses are unpackaged and handled on site.
Refined cheeses made from heat-treated milk	SM OS		100	100 (17)	Absence	It does not appear useful to set hygiene criteria at this stage
Non-refined cheeses made from pasteurised milk	SM OS / Commercial rest.2		100	10 (17)	Absence (18)	The criterion CPS is useful for non-refined pasteurised cheeses if these are unpackaged and handled on site. A limit of 100 cfu/g is recommended.

Safety criterion from Regulation (EC) No 2073/2005
(17) Testing for Staphylococcal enterotoxins at and above 100,000 staph per g.
(18) Criterion to be used only for commercial restaurant services.

I. Raw vegetable products (fruits and vegetables) – Retail

NAME	Scope	Sampling plan	Aerobic microorganisms at 30°C per gram	Lactic flora per gram	*E. coli* per gram	Coagulase + Staphylococci + per gram	Yeasts and moulds per gram	*Salmonella* in 25 g	Comments on the proposed criteria
Raw vegetables without dressing (neither grated nor finely sliced)	SM Manufacture	n=1, c=0	500 000 (3)	-	10	-	-	Absence	The limit proposed for *E. coli* for supermarket manufacture is below the value in the Regulation (100). It would be sensible to harmonise the limits for the *E. coli* criterion to 100.
	SM OS		50 000 000 (3)	-	100	-	-	Absence	
	Community Rest.		50 000 000 (3)	-	50	100		Absence	
Grated or finely sliced vegetables without dressing	SM Manufacture		-	100 000 (3)	10	-	-	Absence	It would be sensible to propose criteria for aerobic microorganisms at 30°C. It would be sensible to harmonise the limits for the *E. coli* criterion to 100.
	SM OS		-	1 000 000 (3)	100	-	-	Absence	
	Community Rest.		-	1 000 000 (3)	50	100		Absence	
Mixture of fresh fruit and f, non-pasteurised fruit juices	SM Manufacture		-	1 000 (3)	10	-	1 000 (3)	Absence	The limit proposed for *E. coli* for supermarket manufacture is below the l the value in the Regulation (100). It would be sensible to harmonise the limits for the *E. coli* criterion to 100.
	SM OS		-	10 000 (3)	100	-	10 000 (3)	Absence	
Mixture of fresh fruits	Fast food		-	10 000 (3)	10	-	50 000	Absence	The criteria proposed for fresh fruit salads in the fast food sector are not consistent with those proposed at the on sale stage (Cf. line above).
Fruit juice from concentrate reconstituted on site	Fast food		-	10 000	10	-	10 000	-	These are not raw fruit and vegetables. It is not entirely appropriate to keep this type of product in this category.

Safety criterion from Regulation (EC) No 2073/2005

(3) Temporary proposed criterion subject to validation in 12 months.