

**GUIDANCE NOTE FOR SAMPLING AND EXAMINATION  
OF PASTEURISED MILK AND CREAM**

This guidance note has been prepared and reviewed by the following representatives of the Lancashire (including South Cumbria) Food Officers Group,, Greater Manchester Food Liaison Group, and Food and Environmental Microbiology Services (FEMS) North West, Preston :

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and reviewed in conjunction with Cheshire and Merseyside Food Liaison Groupss for use by the Local Authorities submitting samples to the North West Regional PartnershipPHLS-NW Food and Environment Service Laboratories.

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## **Glossary of terms**

### **Authorised Officer**

A person (whether or not an officer of the authority) who is authorised, by the Enforcement Authority in writing, either generally or specifically, to act in matters arising under the provisions of the Food Safety Act 1990.

### **On Farm Pasteuriser**

A farm that pasteurises milk and packs the finished product on the farm premises.

### **Milk**

Milk is a complex biological fluid produced by secretion in mammary glands of mammals. This guidance note refers to the milk of cows (bovine milk) only. The milk of cows, ewes, goats or buffalo intended for human consumption.

### **Cream**

The part of cows milk rich in fat which has been separated by skimming or otherwise.

### **Monitoring sample**

A sample taken to check the efficiency of heat treatment and prevention of recontamination.verify the pasteurisation and filling process.

### **Legal proceedings sample**

A sample which is likely to be used as evidence in legal proceedings.

### **Process Hygiene Criteria**

These apply throughout every stage of manufacturing and handling and should be used to assess that production processes are hygienic.

### **Legal proceedings sample Formal sample**

A sample which is likely to be used as evidence in legal proceedings. taken in accordance with the provisions of the Food Safety Act 1990 and Code of Practice No. 7.

### **Food Safety Criteria**

These apply throughout the shelf life of the product and should be used to assess microbiological safety.

### **Statutory sample**

A sample taken and as a formal sample and to be tested in accordance with the procedures set out in The Dairy Products (Hygiene) Regulations 1995 Schedule 3 or 4.

## 1. INTRODUCTION

The requirements for microbiological criteria and heat treatment processes for cows milk and cream, including sampling requirements for Food Business Operators are set out in the following legislation:

- The General Food Regulations (2004)
- EC 178/2002
- Food Safety Act (1990)
- Food Hygiene (England) Regulations 2006
- EC 852/2004
- EC 853/2004
- EC 2073/2005
- EC 2074/2005
- EC 1662/2006
- EC 1664/2006

Although the Dairy Products (Hygiene) Regulations 1995 detail sampling requirements for the examination of milk including cows, sheep, goats and buffalo and cream by the occupiers of dairy premises, However it has been agreed that in view of the risk posed by products from processing establishments, routine sampling by local authorities should also be carried out on public health grounds as part of their sampling programme to meet the requirements of the Food Standards Agency (FSA) Framework Agreement..

The purpose of this guidance is to detail the frequency of sampling, the parameters to be examined and the action to be taken in the event of unsatisfactory results. This guidance is for the examination of cows milk milk and cream and does not include information on other dairy products, or milk derived from other species e.g. sheep. The interpretation of results from the examination of ewe, goat or buffalo milk samples will be interpreted following discussion between the laboratory and Environmental Health Department..

When interpreting the results of samples taken by local authorities, it would not normally be appropriate to interpret them using sample numbers and criteria stated in the regulations (n, c, m, M etc.) as the number of samples submitted is not sufficient to make this meaningful. sampling frequency is not sufficient to make this meaningful. The results could of course be used as part of a local authority assessment in conjunction with the results of sampling carried out by occupiers if the frequency is sufficient.

LDue to some of the recommendations in this guidance local authorities should submit milk and cream samples as detailed in **Appendix 1**.

## **2. SAMPLING AND EXAMINATION OF PASTEURISED MILK AND CREAM FROM PROCESSING ESTABLISHMENTS**

### **2.1 Milk**

#### **2.1.1 Frequency of Sampling**

Processing establishments should be sampled as follows:

i) **On-Farm Pasteurisers**

Each premises should be visited four times a year (quarterly) so as to obtain monitoring samples as detailed in 2.2. Four samples to be examined annually, one to reflect the Statutory Tests detailed in the Regulations plus three monitoring tests.

**Note: At establishments with more than one pasteuriser it is important to sample milk from each pasteuriser on every occasion.**

ii) **Other processing establishments**

At the frequency determined by the local authority.

Note: All samples should be submitted chilled according to the commission decision 91/180/EEC.

#### **2.1.2 Monitoring Milk and Cream Samples Annual “Statutory” Milk Samples**

One sample, comprising two bottles/retail containers, from every type of milk produced i.e. whole milk, homogenised, semi-skimmed and skimmed.

On one occasion each year one bottle/retail container of every type of pasteurised milk (skimmed, semi-skimmed, whole) and cream should be sampled. These samples of milk must be collected directly from the processing establishment, preferably immediately just after during the pasteurisation process and submitted to the laboratory as soon as possible.

On the remaining three occasions a single bottle/retail container of milk only is required. This should be collected from the processing establishment and submitted to the laboratory as soon as possible. The sample obtained should

when possible be representative of all processes carried out on the milk at the establishment, for example semi-skimmed or homogenised milk.

The above samples will be examined as follows: One bottle/container sample is for the pre-incubated colony plate count and one for the other tests including temperature on arrival. These samples will be examined as follows:

Phosphatase test  
Enterobacteriaceae Coliform test  
Pre-incubated colony count

### 2.1.3 Monitoring Milk Samples

A single bottle/retail container of milk is required and wherever possible this should be collected from the processing establishment and submitted to the laboratory as soon as possible. The sample obtained should be representative of all processes carried out on milk at the establishment, for example, semi-skimmed or homogenised milk. These samples will be examined as follows:

Phosphatase test  
Coliform test

- The microbiology results will be interpreted using only the 'M' values specified in EC 2073/2005.
- (Upper Statutory Levels) in the Dairy Products (Hygiene) Regulations 1995 for the Statutory Tests.
- To assist with the interpretation of the phosphatase result for cream samples, it is important to give details of the sample eg. type of cream (double, single, whipping), time and date of production, storage conditions, etc.

**Note: (1)** Results of samples collected from roundsmen or retail will not be interpreted by the laboratory due to the uncertainty of storage history. Routine sampling of retail milk from supermarkets/shops should not normally be carried out. If there are specific problems or complaints, (or if formal action is anticipated) sampling and examination must be discussed with the laboratory.

**Note: (2)** Routine sampling of milk or cream from retail outlets is not justified unless as part of an outbreak investigation or complaint. Submission of retail samples must be discussed with the laboratory.

#### 2.1.42.3 Legal proceedings samples Formal Milk Samples

Formal samples which are likely to be used as evidence in legal proceedings must only be undertaken by Authorised Officers who are adequately trained/experienced in food sampling techniques. Such samples may be taken subsequent to previous unsatisfactory results or as part of an epidemiological investigation and will usually be examined for presence of defined pathogens..

Prior to submitting such a formal sample, the sampling officer must telephone the testing laboratory to notify them of the number and nature of the samples to be submitted, and the examinations required. Legal proceedings samples will be received and handled in the laboratory in the same manner as a formal food sample.

If legal action is anticipated using the Dairy Product (Hygiene) Regulations 1995, the number of sample units comprising the sample (n) is specified.

five samples are required, i.e. 5 is the number of sample units comprising the sample (n = 5).

□ If legal action is anticipated, a ‘dummy’ sample taken at the same time as the legal proceedings test samples must also be submitted in the same transport box, for temperature monitoring purposes. using the Food Safety Act 1990, one sample comprising two bottles as described in **2.1.2** should be submitted.

**Note:** While legal proceedings may be considered under the Food Hygiene (England) Regulations 2006 in relation to milk containing levels of phosphatase which do not comply with EC 1664/2006, it would not be possible to take action where products contain levels of Enterobacteriaceae above those set out in EC 2073/2005. This parameter is defined in the Regulations as a “process hygiene criterion indicating the acceptance functioning of the production process” and is not applicable to products placed on the market.

However, the results of samples examined for Enterobacteriaceae could be used as evidence to support proceedings under other legislation (e.g. establishing and implementing effective controls at critical control points: EC 852/2004, Article 5).

**N.B.** A ‘dummy’ sample taken at the same time as the legal proceedings formal test samples must always be submitted in the same transport box, for temperature monitoring purposes.

## **2.2 Cream**

### **2.2.1 Annual “Statutory” Sample**

A sample of cream should be collected directly from the processing establishment at the same time as collecting the annual statutory milk samples and submitted to the laboratory as soon as possible. To assist with interpretation of results it is important to give details of the sample e.g. type of cream, time and date of production, storage conditions, etc.

These samples will be examined in accordance with the Dairy Products (Hygiene) Regulations 1995. These samples will be examined as follows:

Phosphatase  
Salmonella (25g)  
Listeria monocytogenes (1g)  
Coliform test (guideline) (1g)

**Note: (a)** Routine sampling of retail cream from supermarkets/shops is not justified in the absence of complaints. Submission of any samples must be discussed with the laboratory.

## **2.2.2 Monitoring cream samples**

Monitoring samples of cream from processing establishments are not normally accepted by the laboratory. When these samples are required, discuss with the laboratory prior to submission.

Routine sampling of retail cream from retail outlets is not justified in the absence of complaints. Submission of any samples must be discussed with the laboratory.

Cream samples which are likely to be used as evidence in legal proceedings Formal sampling must be carried out as directed in 2.1.4.

**Note: (b)** Formal sampling must be carried out as directed in **2.1.4**.

## **3. INVESTIGATION OF PHOSPHATASE FAILURES**

### **3.1 Milk Failures**

This guidance relates to milk produced from on-farm pasteurisers and to samples submitted to the Public Health Laboratory in accordance with Sections **2.1.2** and **2.1.3**.

- i) The laboratory will notify phosphatase failures (**see Note: A below**) which exceed the statutory criteria (35500 mU/litreL – Fluorimetric (using a Fluorometric method) assay) by telephone , on the day of

testing. This may result in local authorities receiving notification of failures outside normal working hours. Suitable arrangements should be made to receive and deal with such results.

Note: ii) Milk samples that fail the phosphatase test will only be examined for enteropathogens e.g.i.e. Salmonella, Campylobacter, and E. coli O157. if there is evidence of associated illness in the local community. In addition an aerobic colony count (30°C for 72h) will be performed to assess the general microbiological quality of the milk.

- iii)) The local authority representative should contact the processing establishment immediately and advise that all milk and dairy products should be held. A visit should be made the same day and a detailed investigation carried out. When necessary milk and dairy products should be detained under Section 9 of the the Food Safety Act 1990 or Regulation 27 of the Food Hygiene (England) Regulations 2006.. If it is not possible to identify the problem batch, all milk and dairy products (**see Note: B below**) present should be considered suspect. The farmer may be advised not to release the milk for retail and to arrange for milk to be obtained from another source or to reprocess and gain satisfactory results before release to arrange for milk to be obtained from another source.
- iv)iii) The sampling officer should collect three random samples from the batch of milk originally sampled (if available). These should be from different crates or stacks to represent, as far as possible, the entire production run. A single sample should also be taken from all other batches and types of milk available.

If the original batch is not available take three random samples from the subsequent batch of the same type of milk.

If in doubt consult the laboratory before sampling.

- iv) Arrange with the laboratory to have these samples examined for phosphatase test only as soon as possible during the next working day or the same evening by arrangement with the laboratory if significant public health reasons are evident the same evening. Results will be telephoned to the contact person.
- vi) If the results of these tests are satisfactory release the batch.

- vii)vi) If these follow up samples fail the phosphatase test then the milk held must be discarded or reprocessed at the discretion of the Local Authority. These samples will only be tested for enteropathogens if there is evidence of associated disease in the community.

In the event of illness in the local community, or presence of pathogens consideration should be given to a product withdrawal and a Food Alert (FSA Code of Practice) hazard warning (Code of Practice 16) following consultation with the Consultant in Communicable Disease Control (CCDC). Issues to consider include: quantity of products processed, distribution area and the shelf life of the product.

Where appropriate consideration must be given to the use of Hygiene emergency prohibition procedures under Regulation 8 of the Food Hygiene (England) Regulations 2006 or a Remedial Action Notice under Regulation 9 until the cause of the problem has been identified and remedied. Product withdrawal must also be considered.

- viii)vii) Prior to further use of the equipment, the investigating officer must consider evidence, including remedial work carried out by a competent engineer and the results of further samples submitted by the operator to an independent accredited laboratory.

**Note:** A list of independent laboratories able to carry out phosphatase testing is available detailed in **Appendix 3** from your Food Liaison Group.

- viiiix) Following investigation by the local authority officer and corrective action implemented by the operator, then the investigating officer may wish to take further samples for verification of the phosphatase results. These should be taken from the production run as follows:

- Collect three samples from each of two subsequent batches on two different days.
- Samples should be collected from the beginning, middle and end of the production batch.
- Drawing off milk from the pasteuriser for processes such as homogenisation or separation can affect the flow rate which could lead to incomplete pasteurisation. This should be taken into account when taking these samples.

**Note A:** Phosphatase failures may be genuine i.e. caused by the presence of residual (mammalian) phosphatase – indicating failure of pasteurisation. Phosphatase failures may also be caused by

microbial phosphatase and reactivated phosphatase – both false positive results. The laboratory will conduct tests to confirm genuine (true) positive results and will interpret the results accordingly.

Occasionally it may not be possible to determine the source of phosphatase and these results will be reported as equivocal. Such results should be discussed with the laboratory.

**Note B:** Sampling of dairy products other than milk and cream should not be undertaken until discussed with the laboratory.

### 3.2 Cream Failures

False positive phosphatase results can occur with cream (see **Note: A**). (See Note A, above).

- i) The laboratory will detain presumptive cream phosphatase failure samples overnight if confirmation tests cannot be completed within the normal working day. Hence authorities may be notified of cream phosphatase failures on the day following sampling.
- ii) Cream samples confirmed as failing the phosphatase test due to residual phosphatase will only be examined for enteropathogens i.e. Salmonella, Campylobacter and E. coli O157 if there is evidence of associated disease in the community..

Senior Environmental Health Officers should discuss failures with senior laboratory staff in order to co-ordinate further investigation, sampling and testing before starting any action.

- iii) Cream samples confirmed as failing the phosphatase test due to microbial or reactivated phosphatase (false positives) or results being equivocal, should will be further investigated as follows:

- Microbial phosphatase

Laboratory	- Further examination of failed sample to determine a bacterial source.
	- Discuss results with Environmental Health Department.
EHD	- Repeat sample

- Reactivated phosphatase

Laboratory - Examination for pathogens only if there is an epidemiological reason, or a previous residual phosphatase failed result.

EHD - Repeat sample  
- - Discuss repeat sample failures with laboratory

- All cream re-samples should be taken directly from the pasteuriser and must be accompanied by a sample of the whole pasteurised milk entering the separator and a sample of skimmed pasteurised milk from the same processing batch. When resample results are interpreted, consideration must be given to the results of these milk samples when interpreting the result of the cream sample. Where the milk entering the separator can be shown to have been adequately pasteurised it can be assumed that any cream produced by separation of that milk has also been adequately heat treated.
- To prevent problems with reactivated phosphatase, cream samples taken directly from the pasteuriser should be cooled rapidly e.g. by placing in a coolbox containing crushed ice.

**N.B.** All cream re-samples must be accompanied by a whole pasteurised milk and skimmed pasteurised milk from the same processing batch when resample results are interpreted, consideration must be given to the results of the milk samples when interpreting the result of the cream sample.

iii) Failures should be discussed with Senior EHOs and senior laboratory staff to co-ordinate further sampling and testing before starting any action.

### 3.3 Further advice

‘The guidance notes for on farm pasteurisers’ produced by Lancashire, and Greater Manchester and West Yorkshire Food Officers groups (2007/20) is available on the LACORS website. and Tthe FSA ADAS document – A practical guide for milk producers to the Food Hygiene (England) Regulations (2006) Pasteurised milk – Guidelines for on farm milk processors (1996) also provides Environmental Health Officers with a useful source of information. and advice relating to on farm pasteuriser maintenance and troubleshooting.

#### 4. INVESTIGATION OF ENTEROBACTERIACEAE COLIFORM FAILURES

##### 4.1 Milk Failures

Enterobacteriaceae are often used in food microbiology as indicator organisms to indicate the hygiene status of a process and product. They are readily destroyed by mild heat treatment eg. pasteurisation and their presence in pasteurised milk/cream therefore indicates post heat process contamination from the environment, equipment, or food handlers. The previously used coliform test only detected organisms capable of fermenting lactose whereas the Enterobacteriaceae test also detects important non lactose fermenting organisms including Salmonella, and is a more useful indicator of hygiene.

The purpose of the monitoring Enterobacteriaceae test is for a hygiene check and not intended to be reactive in relation to product withdrawal. Accordingly the Enterobacteriaceae test is a process hygiene parameter in EC2073/2005 not a food safety criterion.

FEMS-NW test methods for Enterobacteriaceae include the following:

- a) **FM04:** A pour plate test procedure. This is able to provide a presumptive positive result after 24 hours and a confirmed result only after 72 hours.
- b) **FM18:** A most probable number test procedure based on ISO 21528-1. This is the reference method detailed in EC2073/2005 and gives a confirmed result after 4 days. This procedure is unable to produce presumptive results.

For the purpose of sampling carried out in accordance with this guidance, method (a) will be used. This will result in presumptive results being notified to local authorities after 24 hours allowing them to contact Food Business operators at an early stage.

Samples will only be examined using Method (b) in relation to Legal Proceeding Samples.

**Action to be taken by local authorities**

The laboratory will notify the local authority of any failures with presumptive Enterobacteriaceae counts of >5/ml by telephone, 18-24 hours after testing.

- (i) Discuss presumptive results with proprietor and advise that confirmed results will not be available for a further two days. Identify possible problems and suggest remedial action including cleaning procedures, personal hygiene etc.
- (ii) If unsatisfactory presumptive results are confirmed, the efficiency of heat treatment, prevention of recontamination, and quality of raw materials should be checked in detail and further samples obtained.

**Note:** If there are several failures, then further detailed investigations should be made. This could include taking milk samples at different stages of the process, submitting six empty capped bottles to check bottle washing procedures for milk failures etc. The empty washed bottles must be taken from different crates to be representative of the bottle washing process. **The samples to be submitted should be discussed with the Laboratory prior to submission.**

The laboratory will notify the local authority of any failures with coliform counts of >5/mL. by telephone. The level of action is dependent on the coliform count.

- ii) Discuss results with proprietor, identify possible problems and agree remedial action  
**csH result.** Submit repeat samples from a batch when corrective actions have been implemented.
- iii) Milk samples examined, with coliform counts of  $\geq 100$ /mL, will be further investigated by the laboratory for the presence of E. coli and enteropathogens i.e. Salmonella, Campylobacter, E. coli O157.
- iv) When enteropathogens have been detected in a milk sample consideration should be given to the use of emergency prohibition procedures until the cause of the problem has been identified and remedied.

**Note:** If there are several failures, then further detailed investigations should be made. This could include taking samples at different stages of the process, submitting six empty capped bottles to check bottle washing procedures etc. **The samples to be submitted should be discussed with the Laboratory PHLS prior to submission.** Statutory tests may also be appropriate.

#### 4.2 Cream Failures

- i) The laboratory will notify the local authority of any failure with coliform counts of >5/mL by telephone.
- ii) Cream samples examined with coliform counts of  $\geq 100$ /mL, will be further investigated by the laboratory for the presence of E. coli and enteropathogens i.e. Salmonella, Campylobacter, E. coli O157.

**Note:** Failures should be discussed with Senior Environmental Health Officer's and Senior Laboratory Staff to co-ordinate further sampling and testing.

## **5. INCREASED FREQUENCY OF SAMPLING BY THE OPERATOR**

Following receipt of unsatisfactory sample results, consideration should be given to the need of increasing sampling by the Food Business Operator (FBO) and checking that the FBO processing check samples (Quality Control) comply with the EC 2073/EC 2073/2005 Enterobacteriaceae process hygiene criteria ( $n = 5$ ,  $c = 2$ ,  $m = <1/\text{ml}$ ,  $M = 5/\text{ml}$ ).operator under the Dairy Product Regulations. Copies of results should be provided to the Local Authority.

## **6. INVESTIGATION OF PATHOGEN FAILURES**

When enteropathogens have been detected in a milk or cream sample, consideration must be given to the use of Hygiene emergency prohibition procedures under Regulation 8 of the Food Hygiene (England) Regulations 2006 or a Remedial Action Notice under Regulation 9 until the cause of the problem has been identified and remedied. Product withdrawal must also be considered.

The laboratory will interpret the result as unacceptable/potentially hazardous and inform the Health Protection Agency (Colindale) and the relevant CCDC as well as the Local Authority.

## **7. RETAIL RAW COWS MILK INTENDED FOR DIRECT HUMAN CONSUMPTION**

i) The sampling frequency for bottled green top milk should, wherever possible, be on a quarterly basis as described for pasteurised milk.

ii) Samples of unpasteurised milk (bottled or retail container) should preferably be collected from the farm (production unit) i.e. farmgate sale or in exceptional cases from the roundsman. These will be examined for:

Aerobic colony count at 30°C for 72h  
Coliform count

These tests have been retained for retail raw milk (Food Hygiene (England) Regulations 2006).

iii) The laboratory will notify unsatisfactory results to the Environmental Health Officer by telephone. Failures will be notified on the final laboratory report.

- iv) Raw milk will only be tested for enteropathogens during outbreak or other epidemiological investigations. **Examination for the statutory pathogens Salmonella and Staphylococcus aureus is at the discretion of the Local Authority but there will be an additional charge for this request.**
  
- iv) The Environmental Health Department should notify the Farming and Rural Conservation Agency (F.R.C.A) Dairy Hygiene Inspectorate (D.H.I) when there is a failure to comply with statutory requirements.
  
- vi) When enteropathogens have been detected in a milk sample, consideration should be given to the use of emergency prohibition procedures (Food Safety Act 1990) or Heat Treatment Notice (Milk and Dairies (General) Regulations 1959, Regulation 20).



## **Appendix 1**

### **SUBMISSION OF MILK SAMPLES**

#### **a) Statutory samples**

These should be submitted on Wednesdays or Thursdays. Monday and Tuesday sampling must be avoided because of the 5 day pre-incubation test which would cause weekend work.

#### **ab) Monitoring samples**

These may be submitted on Mondays, Tuesdays, Wednesdays or Thursdays.

Fridays should be avoided for ROUTINE milk sampling because of potential re-sampling and examination problems caused by failed presumptive Enterobacteriaceae coliform and/or phosphatase tests.

#### **bc) Outbreak investigation and samples following failed results**

These may be submitted any day following discussion with a senior member of the F & E Laboratory.

#### **cd) Legal proceedings Formal samples**

When it is anticipated that a formal sample likely to result in legal proceedings is to be taken, the sampling officer must should contact a food examiner or senior member of the F & E Laboratory to discuss test parameters and ensure prompt receipt and handling.

### **SUBMISSION OF CREAM SAMPLES**

A minimum quantity of cream (150g) must be submitted.

These may be submitted on Mondays, Tuesdays, Wednesdays or Thursdays.

### **TRANSPORTATION OF SAMPLES**

All samples should be submitted to the laboratory as soon as possible, chilled according to the commission decision 91/180/EEC and BS EN ISO 707: 1997 Milk and Milk Products – Guidance on Sampling i.e. 0°C – 4°C.

A FEMS-NW Dairy Product request form Laboratory request forms must be completed so as to clearly indicate the type of milk (skimmed, semi skimmed, whole, etc) or cream (single, double, etc).

A FEMS-NW environmental request form must be completed for the bottle rinse test.

## Appendix 2

### CRITERIA FOR MICROBIOLOGICAL EXAMINATION OF MILK AND CREAM

<u>Raw Bottled Cows Milk for consumption</u>	<u>Statutory Level</u>	
	<u>Statutory level*</u>	
Aerobic colony count	≤ 20,000/mL*	
Coliform count	<100/ml*	
<u>Pasteurised Milk and cream</u>	<u>Target Level</u>	<u>Statutory Level*</u>
		<u>milk</u>
Aerobic colony count (30°C)	≤20,000/mL	None
Pre-incubated plate count (21°C)		≤500,000/mL**
Enterobacteriaceae Coliforms	0≤5/ml (satisfactory), 1-5/ml (acceptable), >5/ml** (unsatisfactory)	
L**		
Phosphatase (Fluorimetric assay)		
≤35500mU/litre***L		

#### Raw Cows Milk

	<u>Statutory level</u>
Aerobic colony count	≤20,000/mL
Coliform count	<100/mL

#### Pasteurised Cream

	<u>Statutory level*</u>
Coliform count	≤5/g***
Salmonella	Absence in 25g
Listeria monocytogenes	Absence in 1g
Phosphatase (Fluorimetric assay)	≤500 mU/L

\* Food Hygiene (England) Regulations 2006 This is the level set in the Dairy Products (Hygiene) Regulations 1995

\*\* This is equivalent to "M" for a single sample failure at the end of the manufacturing process as defined in the EC2073/2005 process hygiene criteria

\*\*\* EC 1664/2006

\*\*\* Based on a single sample (guideline)

### REPORTING AND INTERPRETATION OF THE ALKALINE PHOSPHATASE TEST

EC 1662/2006 specifies that pasteurisation is achieved by a treatment involving a high temperature for a short time (at least 72°C/15seconds) such that the products show a negative reaction to an alkaline phosphatase test.

Regulation (EC) No 1664/2006, Chapter II specifies the criteria for the alkaline phosphatase test. This guidance note recommends the following interpretation:

The level of phosphatase activity is reported as a numerical value of mU/Litre of sample.

- 
- If the phosphatase level is below 100 mU/L the sample is deemed satisfactory.
- 
- If the phosphatase level is between 100 and 500 mU/L, the following interpretation is recommended:
  - The phosphatase level satisfies the statutory requirement; the low level of phosphatase detected is of concern. Investigation, remedial action if necessary and then further sampling is recommended. and the origin of the phosphatase will be determined on a repeat sample if >100mU/L. and pathogen investigations will also be carried out. if the phosphatase level is due to residual phosphatase.
- 
- If the phosphatase level exceeds 500 mU/L, and has been confirmed as residual phosphatase:

The phosphatase level exceeds the equivalent of the standard specified in the Dairy Product (Hygiene Regulations 1995); indicates inadequate processing or contamination with unpasteurised milk.

The level of phosphatase activity is reported as a numerical value of mU/µLitre of sample with the following comment as appropriate:

**Phosphatase level less than 100 mU/litre – Satisfactory result.**

**S.**

**Phosphatase level less than 100 mµ/L – Satisfactory result.**

**Phosphatase level between 100 and 500 mµ/L – Result of concern due to alkaline phosphatase level. Phosphatase level satisfies statutory requirement; low level of phosphatase detected is of concern. Please repeat. For cream samples see note at end of paragraph 3.2.**

**Phosphatase level between 100 and 350 mU/litre – Result of concern due to alkaline phosphatase level. The phosphatase level satisfies the statutory requirement; the low level of phosphatase detected is of concern. Please repeat.**

**Note:** Cream : see 3.2.

(Investigation, remedial action if necessary, and then further sampling is recommended. The origin of the phosphatase will be determined on a repeat sample if >100 mµ/L and pathogen investigations carried out if due to residual phosphatase. Further failures must be discussed with the laboratory).

**Phosphatase level greater than 35500 mU $\mu$ /litreL and confirmed as residual.** -  
*Unsatisfactory result due to alkaline phosphatase test. The level of alkaline phosphatase is due to residual alkaline phosphatase. The phosphatase level exceeds the standard specified in the EC 1664/2006 and Phosphatase level exceeds equivalent of standard specified in Dairy Products (Hygiene) Regs 1995: indicates inadequate processing or contamination with unpasteurised milk.*

Note: Cream : see **3.2**.

**Phosphatase test result equivocal** – *it is not possible to distinguish between reactivated or residual phosphatase in this sample.*

**Borderline results (Uncertainty of Measurement)**

**Phosphatase test result equivocal – it is not possible to distinguish between reactivated or residual phosphatase in this sample.**

- The testing laboratory uncertainty of measurement for the fluorophos test will be applied to samples producing a borderline result i.e. near to the statutory level (350mU/litre). Hence a result range may also be reported with the following comment – *Expanded result indicating range having applied uncertainty.*

*The uncertainty evaluation has been carried out in accordance with UKAS requirements.*

Compliance is achieved if the upper limit is equal or less than the 350 mU/L value. However if the upper limit exceeds 350mU/L, it is not possible to confirm compliance or non-compliance with the statutory level and the following comment will be on the test report – *It is not possible to state compliance – please repeat.*

### **Appendix 3**

## **Laboratories for dairy product sampling**

Eclipse Scientific Group  
Oakland House  
Hortonwood 35  
Telford  
Shropshire TF1 7FR  
Tel: 01952 605566

Fluorimetric testing in accordance with  
EC 1664/2006 (ISO 11816-1). UKAS accredited

**Please note: Inclusion or exclusion does not infer recommendation or otherwise. There may be other laboratories who are able to carry out this work.**