GUIDANCE NOTE FOR SAMPLING AND EXAMINATION OF MILK AND CREAM FROM ON-FARM DAIRIES

This guidance note, previously issued in 2008 by representatives of the Lancashire Food Officers Group, Greater Manchester Food Liaison Group, and Food and Environmental Microbiology Services (FEMS) North West, Preston, was updated to reflect changes in legislation in August 2014. The document was previously considered by:

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Glossary of terms

For the purpose of this document, the following definitions apply:

Authorised Officer

A person (whether or not an officer of the authority) who is authorised, by the Enforcement Authority in writing.

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.

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.

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.

Food Safety Criteria

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

Alkaline phosphatase (ALP)

An enzyme widely distributed in mammals and naturally present in raw milk. The enzyme is inactivated by pasteurisation.

Residual alkaline phosphatase

Alkaline phosphatase enzyme remaining in the product due to inadequate pasteurisation or contamination with raw milk.

Reactivated alkaline phosphatase

Alkaline phosphatase enzyme which was inactivated by pasteurisation but recovered its activity due to storage conditions.

Microbial phosphatase

Phosphatase enzyme produced as a result of microbial activity that is not inactivated by heating at 63°C (milk samples) or 66°C (cream samples) for 30 minutes.

Equivocal

Results are considered equivocal when it is not possible to distinguish between residual and reactivated alkaline phosphatase.

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 Safety and Hygiene (England) Regulations 2013
- EC 852/2004
- EC 853/2004 (as amended by 1662/2006; 1020/2008)
- EC 2073/2005 (as amended by 1441/2007; 365/2010)
- EC 2074/2005 (as amended by1664/2006)

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 and cream and does not include information on other dairy products, or milk derived from other species e.g. sheep. Results from the examination of ewe, goat or buffalo milk samples will be interpreted following discussion between the PHE laboratory and Local Authority.

When interpreting the results of monitoring 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) as the number of samples submitted is not sufficient to make this meaningful.

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 Frequency of Sampling

i) On-Farm Pasteurisers

Each premises should be visited four times a year (quarterly) to obtain the monitoring samples detailed in 2.2.

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.

2.2 Monitoring Milk and Cream Samples

On one occasion each year one bottle/retail container of every type of pasteurised milk (skimmed, semi-skimmed, whole, homogenised) and cream

should be sampled. These samples must be collected directly from the processing establishment, preferably immediately after 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:

Alkaline phosphatase test
Enterobacteriaceae test F23

- The microbiology results will be interpreted using only the 'M' values specified in EC 2073/2005.

- 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: Routine sampling of milk or cream from retail outlets should not normally be carried out unless as part of an outbreak investigation or a complaint.
Submission of retail samples must be discussed with the laboratory.

Results of samples collected from roundsmen or retail will not be interpreted by the laboratory due to the uncertainty of storage history.

2.3 Legal proceedings samples

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 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 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.

Note: While legal proceedings may be considered under the Food Safety and Hygiene (England) Regulations 2013 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 Regulation 852/2004, Article 5).

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 Laboratory in accordance with Section 2.

i) The laboratory will notify phosphatase failures **(see Note: A below)** which exceed 350 mU/litre (using a Fluorometric method) 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: Milk samples that fail the phosphatase test will only be examined for enteric pathogens e.g. Salmonella, Campylobacter, E. coli O157 if there is evidence of associated illness in the local community.

ii**)** The local authority representative should contact the processing establishment immediately and advise that all milk and cream should be held. A visit should be made the same day and a detailed investigation carried out. When appropriate, milk and cream should be detained under Section 9 of the Food Safety Act 1990 or under Regulation 10 of the Food Safety and Hygiene (England) Regulations 2013, if the premises is subject to approval requirements. Alternatively, using the Food Safety and Hygiene (England) Regulations 2013, milk and cream could be Regulation 29 certified. If it is not possible to identify the problem batch, all milk and cream 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.

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. Results will be telephoned to the contact person.

v) If the results of these tests are satisfactory release the batch.

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 enteric pathogens if there is evidence of associated disease in the community.

In the event of illness in the local community, consideration should be given to a product withdrawal and submitting a Food Incident Report (FSA Food Law Code of Practice) following consultation with the Consultant in Communicable Disease Control. 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 Safety and Hygiene (England) Regulations 2013 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.

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 a UKAS accredited laboratory.

viii) Following investigation by the local authority officer and corrective action implemented by the operator, 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.

NB. These samples will only be examined during normal working hours.

Note A: 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 B: 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.

3.2 Cream Failures

False positive phosphatase results can also occur with cream (See Note B, above).

Reactivated phosphatase in particular is more frequently encountered in cream than milk due to the high fat content.

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 enteric pathogens i.e. Salmonella, Campylobacter and E. coli O157 if there is evidence of associated disease in the community.

Local Authorities 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 be further investigated as follows:

Microbial phosphatase

Laboratory - Further examination of failed sample to determine a bacterial source.
- Discuss results with Local Authority.

LA - Repeat sample

Reactivated phosphatase

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

LA - Repeat sample
- Discuss repeat sample failures with laboratory

Equivocal result

LA – Repeat sample

- All cream re-samples should be taken directly from the separator. They 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 re-sample 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 and equivocal results, cream samples taken directly from the separator should be cooled rapidly e.g. by placing in a coolbox containing crushed ice and delivered to the laboratory as soon as possible.

3.3 Further advice

Further advice is available in 'The guidance notes for on farm pasteurisers' (enter this in a search engine for a link to the old LACORS website) produced by Lancashire, Greater Manchester and West Yorkshire Food Officers groups (2007). The FSA document – A practical guide for milk producers to the Food Hygiene (England) Regulations (2006) (reviewed October 2013) is also a useful source of information.

4. INVESTIGATION OF ENTEROBACTERIACEAE 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 EC Regulation 2073/2005 not a food safety criterion.

The PHE test method for Enterobacteriaceae is:

a) **F23**: 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.

The laboratory will notify the local authority of any failures with presumptive Enterobacteriaceae counts of >10/ml by telephone.

Action to be taken by local authorities

(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/containers for a bottle rinse test to check bottle washing procedures or the storage of plastic containers/lids. Empty washed bottles must be taken from different crates to be representative of the whole bottle washing process. **The samples to be submitted should be discussed with the Laboratory prior to submission.**

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 Regulation 2073/EC 2073/2005 Enterobacteriaceae process hygiene criteria (n = 5, c = 0, m = 0/ml, M = 10/ml).

6. INVESTIGATION OF PATHOGEN FAILURES

When enteric pathogens 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 Safety and Hygiene (England) Regulations 2013 or a Remedial Action Notice under Regulation 9 until the cause of the problem has been identified and remedied. Submission of a food incident notification to the FSA (Annex 4 of the Food Law CoP) and product withdrawal must also be considered.

The laboratory will interpret the result as unsatisfactory and potentially injurious to health and inform colleagues within PHE and the LA.

7. 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:
Plate count at 30°C
Coliform count

These tests have been retained for retail raw milk (Food Safety and Hygiene (England) Regulations 2013).

iii) The laboratory will notify unsatisfactory results to the LA by telephone.

iv) Raw milk will only be tested for enteric pathogens during outbreak or other epidemiological investigations.

The LA must notify the FSA when there is a failure to comply with statutory requirements to discuss remedial action.

Appendix 1

SUBMISSION OF SAMPLES

a) Where possible Local Authorities should submit samples using the UKFSS system. Where the Local Authority is not able to use the UKFSS system a PHE Dairy Product request form must be completed

clearly indicating the type of milk (skimmed, semi skimmed, whole, etc) or cream (single, double, etc).

A PHE environmental request form must be completed for the bottle rinse test.

b) **Monitoring samples**

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

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

c) **Outbreak investigation and samples following failed results**

These may be submitted on any day following discussion with a senior member of the Laboratory staff.

d) **Legal proceedings samples**

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

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 – 8°C**.

Appendix 2

CRITERIA FOR MILK AND CREAM

Raw Bottled Cows Milk for human consumption	**Statutory Level**
Plate count	≤ 20,000/ml*****
Coliform count	<100/ml*****

Pasteurised Milk and cream

Enterobacteriaceae	0/ml (satisfactory) 1-10ml (satisfactory), >10/ml** (unsatisfactory)
Phosphatase (Fluorimetric assay)	≤350mU/litre***

* Food Safety and Hygiene (England) Regulations 2013

** This is equivalent to "M" for a single sample failure at the end of the manufacturing process as defined in EC Regulation 2073/2005 process hygiene criteria

*** EC Regulation 1664/2006

REPORTING AND INTERPRETATION OF THE ALKALINE PHOSPHATASE TEST

EC Regulation 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.

EC Regulation 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 with the following comment as appropriate:

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

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***.**

The results of sampling carried out in recent years indicate that where a pasteuriser is operating effectively the level of residual phosphatase in milk should be less than 100mU/l and where the level is higher than this, further investigation should be carried out to determine whether remedial action is required.

Note: Cream : see **3.2**.
Further failures must be discussed with the laboratory.

Phosphatase level greater than 350 mU/litre 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 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) - The testing laboratory uncertainty of measurement for the fluorometric 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*.