

# **GUIDANCE TO FOOD AUTHORITIES IN ENGLAND ON OFFICIALLY TUBERCULOSIS FREE STATUS AND DAIRY HYGIENE LEGISLATION**

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## Scope

1. This guidance has been produced by the Food Standards Agency in consultation with Food Authorities, Defra, The Specialist Cheesemakers' Association and the Institute of Animal Health and updates the version forwarded by the Department of Health to CEHOs with an accompanying letter of 13 March 2000.

2. It provides information and advice for Food Authorities in England who have dairy herds and/or dairy establishments in their area producing raw cows' drinking milk<sup>1</sup> (RCDM) and/or unpasteurised milk-based products. The guidance will be of assistance to those involved with investigations following notification from the Department for the Environment, Food and Rural Affairs (Defra) of the loss<sup>2</sup> of "Officially Tuberculosis Free" (OTF) status of dairy herds.

3. The guidance highlights areas that will be affected by changes when the Dairy Products (Hygiene) Regulations 1995 are replaced by the Food Hygiene (England) Regulations 2005, which take effect from 1 January 2006.

## Introduction

4. Tuberculosis (TB) is an infectious disease of humans and many animal species, caused by some bacteria of the genus *Mycobacterium*. Most cases of human tuberculosis are caused by *Mycobacterium tuberculosis* (*M. tuberculosis*). TB in cattle is primarily caused by *Mycobacterium bovis* (*M. bovis*), which unlike *M. tuberculosis* has a very broad host range.

5. Regular tuberculin testing of dairy herds ensures that most cases of TB in cattle are detected in the early stages of infection, before the development of clinical signs and the shedding of bacteria in milk. *M.bovis* is however responsible for some human infection and the introduction of pasteurisation in the 1930's helped minimise the transmission of TB to man via milk from infected cows. *M.bovis* in humans is now rare – around 40 cases a year

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<sup>1</sup> In this context raw cows' milk also includes raw buffaloes milk.

<sup>2</sup> For the purpose of this guidance and for the purposes of Dairy Hygiene legislation, the herd will have lost OTF status if: a reactor is disclosed by tuberculin testing ("status suspended"); when a reactor is confirmed by post mortem examination and /or bacteriological culture ("status withdrawn"); disclosure of an inconclusive reactor within 3 years of a herd breakdown; or the tuberculin test has become overdue.

which is less than 1% of all TB cases in the UK. Most, if not all of these cases are thought to be due to reactivation of disease acquired in the past.

6. The Dairy Products (Hygiene) Regulations (DPHRs) 1995 (as amended) require that RCDM must come from animals belonging to a herd which is OTF (Schedule 3, part I, paragraph 2). Milk, which does not satisfy this condition, may only be sold for human consumption after it has been heat-treated (regulation 9(10)<sup>3</sup>). The State Veterinary Service (SVS) will notify Food Authorities of conditions in a herd that result in the loss of OTF status.

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<sup>3</sup> From January 1 2006 EC Regulation 853/2004 apply, Annex III , Section IX, chapter 1,1,2(b)

## **Food Authority Enforcement Issues**

### **Action to take on loss of OTF status of a dairy herd**

7. When a dairy herd is placed under TB movement restrictions for whatever reason the Divisional Veterinary Manager (DVM) will send a copy of the herd restriction notice (Form 'TB2') to the relevant Chief Environmental Health Officer (CEHO) with a covering letter. Service of the TB restriction notice effectively suspends the OTF status of that herd.

On receipt of the notification, the Food Authority should ensure that milk from the herd is no longer used for raw milk based products. Milk from the affected herd may be used for human consumption providing it has been pasteurised, or subjected to a stronger heat treatment. Processors making raw milk based products must not use milk from the affected herd and will only be able to continue their production of such products by obtaining an alternative source of supply from an OTF herd. From 1 January 2006, milk from individual reactor animals within a herd may not be used for human consumption in any circumstances.

To give effect to this Local Authority Enforcement Officers will need to:

- a) liaise with the first buyer(s) of the milk (primary wholesaler) to establish where the milk from the affected herd is being transported and delivered;
- b) confirm the use of the milk and the cleaning in place systems for the means of transport ;
- c) ensure that all the milk from the affected herd, and any milk with which it may be mixed, will receive adequate heat treatment before consumption or use for milk based products;
- d) establish whether milk from the herd is being sold as raw cows' drinking milk (RCDM);
- e) establish whether the milk is being offered as part of an on-farm B&B business, or in a farm shop, or at a market stall or to a distributor selling raw milk direct to the ultimate consumer; and
- f) establish whether the milk is being used to make unpasteurised milk-based products either on the particular farm or elsewhere.

8. These investigations may be facilitated by contacting the appropriate regional office of the Dairy Hygiene Inspectorate (DHI) and if necessary the producer and the milk buyer. This may involve liaison with other Food Authorities, including the Food Authority of the first buyer where appropriate.

9. Where the affected farm has heat treatment facilities installed, the Authority should confirm that all hazard analysis controls are in place and working effectively, including adequate heat treatment.

#### **Action to be taken on stocks of raw milk based products following loss of OTF status**

10. Food Authorities will wish to consider the public health implications, via a risk assessment undertaken locally with the Consultant in Communicable Disease Control (CCDC) and the DVM, for products made prior to the herd losing its OTF status. Advice should also be obtained where appropriate from the local Health Protection Agency (HPA). If, as a result of the risk assessment, it is concluded that it would be appropriate to withdraw or destroy such products, a voluntary withdrawal/destruction should be pursued. Enforcement Officers will have to decide on appropriate action based on the circumstances of individual cases. The factors to be taken into account in the risk assessment will include:

11.1 The reasons for the loss of OTF status. This can be due to the disclosure of test reactors, inconclusive reactors only, a slaughterhouse case, or an overdue TB test (see footnote 2).

11.2 Number of reactors identified. This would be the number of reactors in relation to the total herd size and numbers of cattle tested. A single or a low number of reactors in a large herd may represent a lower risk, since it may indicate that the infection has not had time to spread within the herd. A large number of reactors in any herd could indicate either a long term spread within the herd or multiple infections linked to a common source. Herds with larger number of reactors at the initial test are more likely to have additional reactors disclosed at the next test.

11.3 Types of cattle reacting to the test. For example, heifers or bullocks being non-milk-producing animals would be of less significance.

11.4 The number and location of any lesions found at post mortem examination (PME) and tissue culture results.

a) If no TB lesions are found, or lesions are confined to one organ or one part of the body other than the mammary gland, the risk of TB bacilli being present in milk would be considered low. If TB lesions were found in the mammary gland or in more than one organ or part of the body in a lactating dairy cow, the risk of TB bacilli being present in milk would be considered significant. TB bacilli may be present in milk even in the absence of obvious udder disease when the disease has been distributed systemically.

b) Following PME tissue samples are collected from all reactors, including those where no visible lesions were found. Tissue culture takes a minimum of 6 weeks to positively identify *M. bovis*, with approximately 10% of reactors with no visible lesions at PME yielding a positive culture of *M. bovis*.

11.5 Testing history of the individual herd. Aspects to consider include:

- a) time elapsed since the last clear TB test;
- b) previous TB history of the herd; and
- c) the reason for the test.

11.6 The baseline testing frequency for the civil parish. This provides an indication of whether the herd is in a high TB prevalence area. The SVS case veterinary officer will provide expert opinion and judgement of the TB incidence in the locality.

11.7 General herd health and herd bio-security. Consideration should also be given to:

- a) milk somatic cell counts - higher cell counts may indicate a higher likelihood of TB organisms being present in the milk; and
- b) animal trading record for the farm, highlighting numbers brought in, from where and their last TB test date (this is important because it takes a minimum of 6 weeks from the time of infection for an animal to react to the tuberculin test).

11.8 Type(s) of milk-based product and production process. For example, the use of bought in milk may make it more difficult to establish the necessary herd information. Consideration should be given to any scientific evidence, including that provided by the milk processors, that the production process may eliminate the pathogens and that TB organisms are absent from the product.

11.9 Fresh milk products. The shelf life of the product may have been exceeded by the time the post-mortem report or tissue culture results are received.

11.10 Size of the TB restricted herd. The likelihood, severity and duration of TB incidents tends to increase as herd size increases. Although this trend has been identified the affect is difficult to quantify and therefore the other factors detailed above are of greater significance for the risk assessment.

12. Where there is evidence of active disease in an animal, then it is likely that withdrawal of batches of the product produced before the date of TB testing would be appropriate as a precaution. The case Veterinary Officer dealing with the TB incident is often the person best placed to provide information and assist the Food Authority with the risk assessment.

13. The Regulations<sup>4</sup> do not prohibit the marketing of products made before the removal of OTF status. If a voluntary solution cannot be concluded with the producer any action taken will need to be under the Food Safety Act 1990 (as amended) and the General Food Regulations 2004. Enforcement Officers may consider further action under Section 9 of the Act if they suspect that the products concerned fail to comply with food safety requirements as now defined in Article 14 of EC Regulation 178/2002 on general food law. It would however be necessary, for any prosecution to succeed, to prove that an offence had occurred under regulation 4 of the General Food Regulations 2004. This makes it an offence to contravene Article 14 of EC Regulation 178/2002.

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<sup>4</sup> Currently DPHRs, from January 1 2006 EC Regulations 852/2004 and 853/2004 will apply

### **Action to take before OTF problems arise**

14. Food Authorities and the Dairy Hygiene Inspectorate (DHI) should liaise with DVMs to ensure that herds supplying RCDM and/or establishments or processors manufacturing unpasteurised dairy products are tuberculin tested annually. For example, Food Authorities and the DHI should notify DVMs when they become aware of the sale of RCDM for human consumption or the production of unpasteurised dairy products in their area. Food Authorities should advise manufacturers producing unpasteurised dairy products that the law requires that the milk they use may only come from herds classified as OTF. Therefore, enforcement officers should verify that those processors who buy in milk are able to produce evidence that the milk they purchase only comes from dairy herds that are tested annually for TB and are classified with OTF status. Food Authorities should contact the DVM who will be able to supply further information about these issues.

15. Food Authorities may find it helpful to liaise with Local Authority Animal Health and Welfare Inspectors as their responsibilities include checking farm records under animal health legislation.

## Contacts

16. For detailed guidance on dealing with human cases or contacts please refer to the Department of Health's "Guidance on Management of the Public Health Consequences of TB in Cattle". For copies of the guidance telephone 020 7972 5672.

17. If further advice is needed on the action to be taken on stocks of raw milk based products following the loss of OTF status Food Authorities should contact the Food Standards Agency Food Incident Branch, telephone number 020 7276 8448, who will work with the local investigation team.

18. If more information is required on Defra procedures concerning TB controls in England and Wales, you should contact the duty Veterinary Officer at the local Animal Health Divisional Office of the SVS.

19. Additional details may be found on the following web sites:

<http://www.defra.gov.uk/animalh/tb/index.htm>

<http://www.hse.gov.uk/hthdir/noframes/bovine.htm>

[http://www.hpa.org.uk/infections/topics\\_az/tb/infosheets/english.pdf](http://www.hpa.org.uk/infections/topics_az/tb/infosheets/english.pdf)

<http://www.lacors.gov.uk>

## **Annex 1**

### **Legislative Background and Human Health**

#### **Raw cows' drinking milk and unpasteurised milk-based products**

1.1 Schedule 3 Part I paragraph 2 (a) of the DPHRs 1995 requires that RCDM must come from animals belonging to a herd which is officially tuberculosis free. Regulation 9 (10) requires that milk which does not satisfy this condition may only be sold for human consumption after it has been heat treated<sup>5</sup>. The microbiological standards set out in the DPHRs do not specifically mention *M. bovis* but do require that milk based products shall not contain pathogenic micro-organisms or their toxins in such a quantity as to affect the health of the ultimate consumer (DPHRs 1995, Schedule 6, Part I paragraph 1).<sup>6</sup>

1.2 Where Food Authorities investigating a notification of the loss of OTF status become aware that milk is being sold raw for direct human consumption, they must consider taking action (under Regulation 9(10) of the DPHRs)<sup>7</sup> to ensure that milk from herds that have lost their OTF status is heat treated.

1.3 Under the Milk and Dairies (General) Regulations 1959 (as amended) the Proper Officer may consider serving a notice<sup>8</sup> to the occupier of the premises specifying that no milk may be sold for human consumption unless it has been treated. The "Proper Officer" of the local authority will be an officer appointed for that purpose by the Food Authority under the 1972 Local Government Act. The officer has to be reasonably capable of forming a view on the evidence provided but does not have to be medically qualified. The "Proper Officer" serves a notice under Regulation 20 of the Milk and Dairies (General) Regulations 1959. A notice served regarding TB, or suspected TB, will continue in force until it is withdrawn. The DVM should notify the CEHO when herd restrictions have been lifted

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<sup>5</sup> From January 1 2006 EC Regulation 853/2004 apply, Annex III Section IX, chapter 1,1,2(b)

<sup>6</sup> From January 1 2006 EC Regulation 852/2004 Annex II Chapter IX will apply

<sup>7</sup> From January 1 2006 EC Regulation 853/2004 apply, Annex III Section IX, chapter 1,1.3

<sup>8</sup> A notice is any formal written communication from the Food Authority to the occupier of the premises (sometimes known as a Heat Treatment Order, see Annex 3)

and the OTF status restored. The notice should be withdrawn forthwith once the herd has regained its OTF status.

1.4 The Food Hygiene Regulations (England) 2005 will revoke the Milk and Dairies (General) Regulations 1959. These regulations come into force on 1 January 2006 and after that date Food Authorities will need to ensure that milk from herds that have lost their OTF status may only be used for human consumption after it has been heat treated<sup>9</sup>. A draft form is provided at annex 4, which may be used by Food Authorities to remind milk producers of this requirement.

1.5 While the law requires that raw milk based products may only be manufactured with milk from herds classified as OTF the Regulations do not prohibit the marketing of products made before the removal of OTF status. If a voluntary solution cannot be concluded with the producer any action taken will need to be under the Food Safety Act 1990 and the General Food Regulations 2004 (see paragraph 13).

### **Cases of human illness**

1.6 In the event of a CCDC being notified that a person(s) has confirmed bovine TB, and the infection is thought to be recently acquired, the CCDC should ascertain any connection with cattle that might indicate the infection could have been caught from an animal source or could be passed to animals. If so they should inform the Food Authority. If there is a risk that a herd and/or other farm stock could be infected then the enforcement officer should notify the DVM so that checks can be made on the herds. It may also be appropriate to notify other relevant Food Authorities, local farmers, dairies and producers, milk buyers or distributors that might be affected (with due regard for patient confidentiality).

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<sup>9</sup> From January 1 2006 EC Regulation 853/2004 Annex III Section IX, Chapter 1, 3 (a) will apply

## **Annex 2**

### **Animal Health Issues and the Role of the SVS (Defra)**

#### ***M. bovis* infection in cattle**

2.1 Tuberculosis (TB) in cattle is caused by *Mycobacterium bovis* (*M.bovis*) and bovine TB can affect other species such as deer and badgers. Humans can also be affected, although this is now rare in the UK. In the past infection from raw milk occurred, but now with regular testing of herds, slaughter of reactors and milk pasteurisation, human cases are relatively rare and usually thought to be due to the reactivation of disease contracted earlier, for example before milk pasteurisation was widely in use, or, occasionally, infection contracted abroad. Regular testing of cattle on the farm detects most cases early, before the organism is shed in milk. The bacteria can be inhaled in aerosols from the lungs of infected cattle, or ingested through drinking contaminated raw milk or consuming contaminated unpasteurised milk-based products.

2.2 In recent years, TB in cattle has increased in the UK in both numbers and geographic spread. Since the early 1980s the number of herds reported each year where the OTF status has been withdrawn has steadily increased. This initially affected mainly the southwest of England, but in recent years has spread to parts of South Wales and the West Midlands.

2.3 The routine tuberculin skin testing of herds is a key part of TB control in cattle in the UK. Any animal showing a positive reaction (i.e. a “reactor”) to this test is slaughtered and compensation paid. Slaughtered reactors undergo post-mortem and lymph node and other tissue samples are collected for culture of the organism to identify the strain of *M. bovis* responsible for the incident. Less than half of positive test reactors are found to have visible lesions or a positive culture for *M.bovis*. The Meat Hygiene Service also routinely examines all carcasses at abattoirs for macroscopic lesions of TB as part of general meat inspection.

#### **Routine testing of herds**

2.4 Most TB testing in Great Britain is carried out by Local Veterinary Inspectors (LVIs). These are veterinarians in private practice appointed by Defra to carry out specific statutory duties. Veterinary Officers of the SVS

undertake some of the follow-up tests in herds under TB restrictions and the re-testing of inconclusive reactors. The SVS is responsible for the day to day administration of the tuberculin testing programme, the supervision of LVIs and the management of TB incidents. The latter includes notification of a new TB incident to the relevant environmental and public health officials. Where individual farmers have agreed with the local Defra DVM that they wish to pay for private testing outside of the routine testing, the farmer must notify the DVM of the results accordingly.

2.5 Farmers may wish to carry out private tests, for instance on purchased animals, to clarify their TB status. Additionally, more frequent testing could be viewed as providing an early indication of problems for producers of unpasteurised cows' milk and raw milk-based products intended for consumption in that state. Pre-movement TB testing of any purchased cattle would provide an additional safeguard against the introduction of infection in the herd.

2.6 Most British cattle herds are routinely tested at 4-year intervals, but in some parts of the country, where the incidence of confirmed TB herd breakdowns is greater, TB testing is carried out more frequently. Cattle herds in Scotland, North Wales and most of the North and East of England remain on 4-yearly testing. There are some parts of the country where testing can be annually, 2-yearly or 3-yearly.

2.7 The frequency of routine TB testing is broadly based on the incidence thresholds set out in Council Directive 64/432/EEC (as amended). This testing is essentially for animal health/disease control purposes, and Defra is responsible for the testing policy. The default testing frequency in any given parish is set by the DVMs according to the number of confirmed TB herd breakdowns. In general, the higher the incidence of confirmed herd breakdowns of unexplained origin in a given parish, the shorter the interval between two consecutive routine TB tests for all the herds in that parish. Furthermore, DVMs can place individual herds on an annual TB testing regime on animal or public health grounds, regardless of the default routine testing frequency for their parish. Examples of such herds are: cattle dealers' and bull hirers' herds, herds with a regular intake of cattle from areas with a high incidence of TB, retailers of RCDM and, where this information is available to the DVM, suppliers of milk for the manufacture of unpasteurised dairy products.

## **Finding a TB reactor**

2.8 Disclosure of tuberculin test reactors at a routine herd test is the most common reason for the service of TB restrictions by the SVS, but other situations may also lead to the suspension of the OTF status of a herd. These include detection by the Meat Hygiene Service of suspect lesions of TB at routine meat inspection in the abattoir; disclosure of inconclusive reactors within three years of the resolution of a confirmed TB incident; or the tuberculin tests becomes overdue. When a dairy herd is placed under TB movement restrictions for whatever reason the DVM will send a copy of the herd restriction notice (Form 'TB2') to the relevant Chief Environmental Health Officer (CEHO) with a covering letter. Service of the TB restriction notice effectively suspends the OTF status of that herd. Automated letter distribution systems are being introduced but EHOs and the DVM should develop strong working relationships to ensure effective communications at a local level are established.

2.9 All tuberculin test reactors are sent under licence for compulsory slaughter. When reactors are slaughtered and herd restrictions applied, the DVM will make arrangements to re-test the herd at 60 day intervals until negative herd tests are obtained (one test when disease is not confirmed, two tests when confirmed). Following a programme of clear skin testing, movement restrictions will be lifted, thereby restoring the herd's OTF status. The DVM will notify the CEHO when the OTF status of a dairy herd has been regained.

## **Laboratory confirmation of TB**

2.10 TB incidents (also known as herd breakdowns) are confirmed when at least one reactor animal in that herd presents with visible lesions of TB at post-mortem examination and/or when *M. bovis* is isolated by bacteriological culture from selected tissue samples. Additionally, a TB incident can also be confirmed when suspect lesions are found in carcasses of clear testing cattle during routine meat inspection and those lesions yield *M. bovis* on culture.

2.11 As indicated in 2.9 above, all reactors are slaughtered and undergo post-mortem examination for confirmation of infection. On average, less than half of these animals are found to have visible lesions on post-mortem examination. The remainder are called "no visible lesion" (NVL) reactors. A small proportion of those NVL reactors may be due to false

positive tuberculin tests, but the majority represent cattle at an early stage of infection, where the lesions of TB are too small to be detectable by visual inspection of the carcass. The SVS will collect appropriate tissue samples for submission to the Veterinary Laboratories Agency, where bacteriological culture of *M. bovis* will be attempted. In NVL reactors, a pool of apparently normal lymph nodes is collected to attempt the isolation of *M. bovis* by bacteriological culture and thus confirm the infection. In reactors with visible lesions, infection is automatically confirmed and the main reason for taking samples of the lesions is to undertake molecular typing of the *M. bovis* strain responsible for the incident. The outcomes of the post-mortem and bacteriological culture determine the number of 60-day interval tests that must be carried out in the remainder of the herd before TB restrictions can be lifted. Laboratory confirmation of TB by culture will take a minimum of 6 weeks. It could take longer if samples are contaminated.

- 2.12 The DVM will notify CEHOs of all TB incidents (whether subsequently confirmed or not) in dairy herds so that checks can be made and action taken under the DPHRs<sup>10</sup>. The DVM will notify the CCDC of confirmed TB incidents in any herd, for human health screening purposes. A courtesy copy of the notification of confirmed TB is often sent to the CEHO. In the unlikely event of TB of the udder being found on post-mortem examination, both the CEHO and the CCDC will be notified by the DVM.

### **Inconclusive Reactors**

- 2.13 On occasions the result of the skin test on animals will be in an intermediate range between positive and negative. These animals are classed as inconclusive reactors (IRs). Cattle may react in this way for a number of reasons including stress or exposure to other diseases but experience has shown that the majority of inconclusive reactions are non specific and resolve at the first or second retest.
- 2.14 In herds where there has been a recently confirmed TB breakdown (within the last 3 years), finding an IR results in the whole herd being placed under restrictions and the OTF status of the herd is suspended. CEHOs will be notified of these situations and all milk from the herd must be heat treated.

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<sup>10</sup> From January 1 2006 EC Regulation 853/2004 will apply

- 2.15 In herds where there is no recent history (within the last 3 years) of confirmed TB, IR animals are isolated and re-tested after 42 - 60 days. There are no restrictions regarding milk from the animals and OTF status of the herd is not compromised. If the inconclusive cattle retest negative, the DVM will permit the animal to rejoin the herd. If the second test is also inconclusive a third and final test will be carried out after another 42 – 60 days and unless this test is clear the animal will be reclassified as a reactor and slaughtered. The herd will then be classed as a confirmed TB breakdown.
- 2.16 If IRs re-test positive at either stage they are classed as reactors, OFT status is lost and the animal(s) will be slaughtered. Post-mortem examinations are carried out on all carcasses at the slaughterhouse and samples will be sent for culture.



for a further period or periods of twenty-four hours. In any other case the notice will operate until it is withdrawn. The notice must be withdrawn forthwith upon the officer by whom it was served being satisfied that the milk in respect of which it was served is no longer likely to cause disease through infection.

## Annex 4

Model form for use following loss of OTF status for milk producers  
(Only for use on or after 1 January 2006 if required)

**NAME OF OCCUPIER  
ADDRESS**

**NAME OF LOCAL AUTHORITY  
ADDRESS  
TELEPHONE NUMBER**

### **Milk from herds that have lost their Officially Tuberculosis Free (OTF) Status and milk from TB reactor animals**

When a dairy herd is placed under TB movement restrictions, the herd effectively loses its Officially Tuberculosis Free status. This occurred to your herd when the TB2 notice was served on [xxxx] by [xxxx]. Milk from the above premises must therefore be pasteurised or subjected to a stronger heat treatment before it may be sold for human consumption, or used in the manufacture of products for human consumption. Milk heat treated in such a way will show a negative reaction to the phosphatase test. In addition, milk from any individual reactor animal must be withheld and must not be used for human consumption

Further please be advised that any person who sells or uses milk or milk-based products in breach of Article 4 (1) of Regulation (EC) 853/2004 may be convicted of an offence under the Food Hygiene (England) Regulations 2005. The legislative rules detailing the herd health requirements for raw milk production are contained in Annex III, Section IX, Chapter I of Regulation (EC) No. 853/2004. Annex III, Section IX, Chapter I, 3(a) requires that raw milk from animals that do not belong to an Officially Tuberculosis Free herd may, with the authorisation of the competent authority, only be used for human consumption after having undergone a heat treatment such as to show a negative reaction to the phosphatase test.

To safeguard your own health, that of your family or staff it is strongly recommended that you do not drink or use unpasteurised milk in your home.

Signed.....

Environmental Health Services

Date .....

