Guidance for producers of raw drinking milk for direct human consumption

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Revision history

Revised	Purpose of revision and paragraph number	Revised by
March 2020	Version 1	Christine Kelleher
April 2020	Revisions to paragraphs 45-50 and 55-68	Christine Kelleher

Summary

Intended audience:	Food business operators (FBOs) producing raw drinking milk (RDM) of all species
Which UK nations does this cover?	England and Wales
Purpose:	This guidance is intended to provide advice on both legal requirements and best practice relating to the production and placing on the market of RDM from all species intended for direct human consumption. This guidance does not extend to dairy products made using RDM.
Legal status:	This document has been produced to provide guidance on the legal requirements of food safety and hygiene legislation relevant to the production and distribution of RDM. A full list of the relevant legislation can be found in Annex 1. It also includes examples of best practice.
Key words	• Raw Drinking Milk/RDM • Dairy products • Hygiene and food safety • Labelling and composition • Pathogens
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Contents

Introduction

1. Given its potential health implications, raw drinking milk (RDM) is considered as a risky food by the Food Standards Agency. Enhanced measures are therefore in place to safeguard public health. Should these measures not prove effective then the FSA will consider whether further regulatory or legislative measures may be required for the RDM sector.

2. There has been a significant increase in the number of RDM producers in recent years and thus a significant increase in RDM being placed on the market. Between 2015 and 2017 there were five outbreaks involving human illness linked to RDM, while prior to 2015 there were no outbreaks for over 12 years. In these outbreaks there were a total of 103 reported cases, 40 of which were laboratory confirmed. Children were made unwell in all five outbreaks and some were hospitalised.

3. The Food Standards Agency (FSA) has produced this guidance document to help food business operators (FBOs) who are producing RDM to control these risks and comply with the relevant legislation

4. It is the responsibility of the FBO to ensure that the RDM they are placing on the market is safe to drink. All RDM producers must adhere to the legal requirements.

5. While there have been no legislative changes, the FSA are being more explicit in the controls that should be implemented by producers so that they can demonstrate compliance with the current legislation and try and ensure their product is as safe as possible. The two main controls being emphasised within this guidance are:

    - to have an effective and verified Food Safety Management System (FSMS) in place which is a legal requirement
    - to commit to best practice in carrying out regular tests for pathogens which can be found in RDM

6. Even with good controls in place, RDM remains an inherently risky product. The FSA advises that RDM may contain harmful bacteria that can cause food poisoning. Consumers who have a weakened immune system and are particularly vulnerable to food poisoning should not consume unpasteurised milk, colostrum, cream, or products made from raw milk. Vulnerable groups include children,

pregnant women, older people and those who are unwell, have chronic illness and/or are immunocompromised.

Intended audience

7. This guidance is intended for FBOs who are producing RDM of all species for direct human consumption. While this guidance is not aimed at enforcement authorities (EAs), it may be referenced by them to inform their official controls.

8. For the purposes of this guidance, FBO refers to producers, including farmers, who produce RDM of any species for direct human consumption.

Legal status of guidance

9. These guidance notes have been produced to provide guidance on:

- the legal requirements of Regulation (EC) No 852/2004 on the Hygiene of Foodstuffs, The Food Safety and Hygiene (England) Regulations 2013, The Food Hygiene (Wales) Regulations 2006 and other applicable regulations as detailed within the list provided in Annex I.

- best practice guidance. You are **not** required by law to follow best practice guidance. While some aspects of the guidance are best practice, they may form a critical part of your food safety management system which is a requirement.

10. The UK exited the EU on 31 January 2020. There is now a transition period until the end of 2020 while the UK and EU negotiate additional arrangements. During this period EU food and feed safety law will continue to apply. The European Union (Withdrawal) Act 2018 provides that, from 1 January 2021, certain directly applicable legislation of the European Union (EU) will be converted into UK law.

11. The guidance notes on legal requirements cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances. If you do follow the guidance notes they will help you to comply with the law. You are not required by law to follow best practice guidance. All guidance on best practice is identified in shaded boxes, with a heading of Best Practice:

Best Practice

All best practice guidance is clearly identified within this document by this style of format.

12. While some aspects of this guidance are best practice, the evidence base indicates that improved controls are needed to provide better risk management of RDM. An important aspect of these improvements is the need for FBOs to take greater responsibility in ensuring that the RDM they produce is safe when they supply it to the final consumer as well as being aware of the risk the product poses to vulnerable groups. This issue was considered by the FSA Board, and the following is a quote from the June 2018 Board paper:

"We propose the development of a set of values [including number and seriousness of outbreaks associated with RDM and proportion of failed hygiene indicator samples]contravention of which would trigger consideration of further measures by the FSA, including as appropriate at Board level, should that be necessary, with the options of further action, including legislation if necessary, to protect public health."

Definitions

13. A full glossary of legal definitions and other technical terms used within this guidance has been provided in Annex V.

Registration

14. Regulation (EC) No 852/2004, Article 6 requires that all businesses producing milk or selling RDM must be registered as a food business. New producers must complete a food business registration pack which can be obtained from the FSA. See details provided below. The FSA will notify the relevant Local Authority (LA) of your registration.

15. FSA Dairy Hygiene Inspectors (DHIs) and LAs carry out food hygiene official controls at dairy production holdings supplying RDM direct to the final consumer. The FSA and the LA both have enforcement responsibilities for different aspects of official controls in relation to the production of RDM. The FSA DHIs carry out hygiene inspections at production holdings of all species through a series of combined hygiene audits and inspections, which routinely take place twice per

year. Inspections of RDM bottling and filling operations and other relevant aspects of these operations will be undertaken by the LA. Further detail on the split of enforcement in these establishments can be found in Annex II.

16. Once registered, the FSA will notify the LA of any operations that fall under its official control responsibility. The LA will then contact you to arrange to assess operations over which they have jurisdiction. The EAs will liaise with each other and co-ordinate visits when appropriate.

17. Registration details of all RDM establishments, together with their compliance rating following the most recent dairy hygiene inspection, are published on the FSA website.

18. Article 6 also requires the FBO to update the EA of any significant change to their business. If your premises is already registered as a food business and you wish to place RDM on the market, this is considered as a significant change to your current activity. You are therefore required to notify the FSA of your intention to start selling RDM by contacting the FSA's Registrations and Approvals team using the contact details below. Again, this notification will be shared with the relevant LA.

Food Standards Agency (Approvals & Registrations Team)
Kings Pool
Peasholme Green
York
YO1 7PR
Tel: 01904 232060
Email: approvals@food.gov.uk

Application forms can be found on the FSA website.

Best Practice

All new production holdings are asked to register with the FSA at least 28 days before they intend to start operating.

Existing production holdings are recommended to notify the FSA 14 days before they intend to place RDM on the market. This is to allow a DHI to visit to ensure adequate procedures are in place and implemented to help to produce a safe product. If the FBO fails to provide advance notification and a subsequent inspection by the EA finds inadequate procedures in place or unsafe product being produced, formal action may be taken against the FBO.

Post registration/notification inspection of dairy production holdings

Once you have either registered as a new business or notified the FSA that you intend to place RDM on the market, the FSA strongly recommends that you do not start selling until a DHI has carried out a visit and assessed your food safety controls. This visit will be made within 14 days of notification.

What to expect from your first DHI visit

19. The aim of the initial visit made by the DHI is to assess compliance with food law for this activity, specifically the:

- implementation of an effective FSMS to control food safety hazards
- evidence that the FSMS has been adequately validated to ensure it is adequate
- evidence that verification procedures are in place to demonstrate that the FSMS is operating effectively and that the product is safe
- temperature control of the final product
- shelf life determination
- labelling of RDM and proposed sales routes
- general farm hygiene conditions, hygiene facilities, type of parlour/milking, milking operations, animal cleanliness
- general management of the farm and confidence in management
- systems in place are effective and appropriate food safety controls are being applied to ensure the RDM is safe for consumption
- procedures and documentation are in place to ensure milk from animals under medical treatment is not placed on the market
- procedures to identify animals whose milk must not go for human consumption
- pest control procedures are in place

- staff are adequately trained for their role
- structural integrity of the premises, particularly the bottling area
- cleaning procedures and the chemicals used
- evidence that water being used is of the required standard

20. The purpose of the EA visit is to verify your compliance with the legal requirements, and to take appropriate action where compliance cannot be adequately demonstrated. The responsibility for ensuring that RDM is safe and to demonstrate that adequate practices and procedures are in place to achieve this lies with the FBO.

Food Safety Management System

21. The responsibility for the production and supply of safe food, including RDM, lies solely with the FBO. Failure to implement adequate systems may result in enforcement action being taken.

22. Regulation (EC) No 852/2004, Annex I, Part A places the responsibility on the FBO to ensure that their milk does not present a health risk to consumers. They must demonstrate to the EA what measures have been taken to ensure they have a FSMS in place which is designed to identify and control all relevant hazards associated with the production of RDM.

23. Having a documented FSMS will ensure the FBO has identified the hazards within their processes and will assist them in implementing the necessary controls to try and ensure a safe product. It will also help the FBO to demonstrate how they comply with food safety and hygiene legislation.

24. The FSA considers that to meet their obligation, FBOs should follow these seven steps when designing their FSMS:

Food Safety Management System process steps

1. Identify the hazards in the primary production operation. Identify what could go wrong, meaning the hazards that must be prevented, eliminated or reduced to an acceptable level

2. Identify which controls are essential to ensure that those hazards are controlled and the RDM produced is safe

3. Set parameters for each of these essential points that let the FBO know when the hazards aren't under control

4. Monitor the hazards at these essential points so it is known when the hazards are not under control. This will help to prevent unsafe product being placed on the market

5. Take action when the hazards aren't under control. Decide what to do, how to put it right and how prevent it happening again

6. Prove or validate that the FSMS would be effective once applied. Establish procedures to demonstrate that the system can control the hazards. Establish procedures to determine that the system is being applied properly

7. Establish documentation and record keeping.

This is not an exhaustive list and the DHI may discuss other options with you at the time of inspection.

Best Practice

If the FBO does not have the knowledge or experience to produce and document an effective FSMS, they should seek expert advice.

Further advice and guidance on developing a documented FSMS can be found on the FSA website.

Microbiological safety

Plate count and coliforms

25. Under Schedule 6 of The Food Safety and Hygiene (England) Regulations 2013 and The Food Hygiene (Wales) Regulations 2006, FBOs are required to ensure that RDM meets the following microbiological standards:

- plate count at 30°C (CFU/ml) ≤ 20,000
- coliforms (CFU/ml) < 100

26. Any person who sells RDM that are in breach of the above parameters commits an offence.

Best Practice

FBOs are recommended to sample and test their RDM for the indicator organisms listed above as part of their verification procedures to demonstrate that their FSMS is working effectively.

If an FBOs product is not meeting these standards, they can try to improve subsequent test results by ensuring that their herd is in good health and that udder health and hygiene is being maintained. They can also improve levels of cleanliness throughout their process and ensure that good hygienic practices are being maintained. For more detail on good hygiene practices, please refer to our milk producer guide on the FSA website.

A failed sample result for these parameters demonstrates a breakdown in controls and indicates that the RDM may not be safe for consumption. Once a failed sample result has been received, it is recommended that the FBO cease the distribution of RDM until corrective actions have been taken and subsequent sample results demonstrate that the process is back under control and that the product is within legal parameters.

On receipt of a failed sample result the FSA will carry out a full investigation, in conjunction with the LA where appropriate. Where inadequate and non-compliant practices and procedures are found, the FBOs will be notified and enforcement action will commence, following a graduated approach. Follow up samples will be taken by the relevant EA and further sample failures will result in an escalation of enforcement action.

Somatic cell count and plate count

27. As well as complying with specific requirements for RDM laid down in national regulations, FBOs must comply with the requirements for raw milk laid down in EU law. Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, Part III requires that all raw milk must meet the following requirements for somatic cell

count (SCC) and plate count (at 30°C) regardless of whether it is intended for further processing or to be consumed raw:

Raw cow's milk

Somatic Cell Count – The rolling geometric average must be equal or below 400,000 per ml (over a three-month period, with at least one sample per month)

Plate Count – The rolling geometric average must be equal or below 100,000 per ml (over a two-month period, with at least 2 samples per month)

Raw milk from other species

Somatic Cell Count – There is no legal requirement to sample for SCC

Plate count for all raw milk – The rolling geometric average must be equal or below 1,500,000 per ml (over a two-month period with at least two samples per month)

Plate count for raw milk intended to produce non-heat-treated products, for example cheese – The rolling geometric average must be equal or below 500,000 per ml (over a two-month period, with at least two samples per month)

28. RDM must be tested for SCC (where required) and plate count by either

- the FBO producing the milk
- the FBO collecting or processing the milk (first purchaser)
- a group of FBOs (cooperative)
- a national regional control scheme

29. For the majority of FBOs, including those producing milk for further processing as well as for direct sale, this testing is carried out by the FBO collecting or processing the milk – the milk first purchaser. In these cases, the milk first purchaser will report these results to the FBO and the FSA.

30. If FBOs are only providing RDM to the final consumer and do not sell to a first purchaser, they will need to consider how they are going to demonstrate compliance with the criteria and undertake such testing themselves.

31. If an FBO becomes aware that milk fails to comply with the above criteria, they must inform the FSA in the case of raw **cows** drinking milk and the LA in the case of RDM of all other species. The FBO must take measures to correct the situation.

32. In accordance with Commission Implementing Regulation (EU) 627/2011, Article 50, if the FBO has not taken corrective action and brought SCC and plate count within the legally required parameters within 3 months of notifying the EA, the placing of all raw milk including RDM on the market is to be suspended. This suspension will remain in place until the FBO can demonstrate that levels are compliant.

Best Practice

Plate count and SCC are indicators of disease and/or hygiene. To avoid sample fails for these parameters and to rectify breaches of these standards when identified, the health of the herd and hygiene controls should be assessed and improved where necessary. In particular, udder health and hygiene should be maintained. For further detail on these controls, please refer to our milk producer guide on the FSA website.

If the legally required levels for plate count and/or coliforms are exceeded, the FSA recommends that sales should stop as this indicates a lack of control over the process and that the FSMS is either ineffective or is not being applied properly.

It is recommended that the FBO investigates and takes appropriate corrective action to rectify the issue. Further sampling by the FBO is needed to verify that the plate count and/or coliform levels are no longer greater than the legal requirements.

It is recommended that RDM is not placed on the market until an investigation has taken place and sample results verify that the levels are within the legal parameters.

Pathogens

33. Article 14 of Regulation (EC) No 178/2002 requires that food shall not be placed on the market if it is unsafe.

34. FBOs supplying RDM direct for human consumption will need to consider how they will demonstrate that the hygiene controls they have in place via their FSMS are effective and working properly and how they can demonstrate that their product is safe. The process of validation and verification forms part of the FSMS process described above and is vital to ensuring that the system works.

Best Practice

In addition to *Listeria monocytogenes,* which is discussed further below, the following harmful bacteria/pathogens have been associated with samples of raw milk and guidelines on the safe parameters for these pathogens have been determined.

- *Salmonella* spp. must be absent in 25ml
- *Campylobacter* spp. must be absent in 25ml
- Shiga toxin producing *E. coli* (STEC) must be absent in 25ml[1]
- *Coagulase positive staphylococci* below 10^4 CFU/ml (however levels between 20 and 10^4 CFU/ml may indicate poor process hygiene and temperature controls and would prompt an investigation into the likely cause)

The FSA considers that microbiological sampling and testing has an important role in validating and verifying that the controls applied are effective.

As part of the validation of their FSMS, it is recommended that FBOs provide one full set of satisfactory test results to the FSA. This could include plate count, coliforms and those pathogens listed above.

It is also recommended that the FBO devise and apply a sampling and testing regime that provides ongoing assurances that the FSMS is effective. The frequency of testing would depend on the nature of the business, the risks associated with the production systems and the controls

[1] Testing for *E. coli* O157 rather than all STEC provides reduced protection for public health. We acknowledge the burden on businesses and are working with industry and laboratories to establish a pragmatic approach that balances the need to protect public health and the sampling and testing burden

that are already in place. When devising a sampling regime, an FBO would need to determine the frequency as part of their FSMS.

To ensure any sample taken is representative of the final product being consumed, it is recommended that samples be taken from the final container or the vending machine.

The use of an appropriately accredited laboratory, for example UKAS (United Kingdom Accreditation Service) accredited would ensure that appropriate testing methods are used, and results are valid and reliable.

It is recommended that FBOs report any routine sample results that fail to meet the required standards to the relevant EA as soon as they are available. This would be the FSA for raw **cows** drinking milk and the LA for RDM of all other species.

35. If the FBO has reason to believe that the product is unsafe, they are obliged under Regulation (EC) No 178/2002, Article 19, to withdraw or where necessary recall product batches from the market. Further guidance on withdrawal and recall can be found towards the end of this document.

Listeria monocytogenes

36. Regulation (EC) No 2073/2005 establishes food safety criteria for various pathogens and provides limits for *Listeria monocytogenes* in ready-to-eat food such as RDM. Annex I, Chapter 1, point 1.2 and 1.3 apply.

37. Where RDM has a shelf-life of **4 days or less** it may be assumed, providing that milk is kept under refrigeration, that *Listeria monocytogenes* will not grow. However, *Listeria monocytogenes* may be present in the product even if it can be assumed that it will not grow during this shelf life. Therefore, FBOs must demonstrate that *Listeria monocytogenes* does not exceed the limit of 100 CFU/ml throughout the proposed shelf life.

38. When the FBO wishes to allocate a shelf-life of **longer than 4 days** they need to demonstrate that *Listeria monocytogenes* is **either**

- absent in 25ml before it leaves the control of the FBO **or**

- prove that it will not exceed 100 CFU/ml throughout the proposed shelf life of the product. This must be done in accordance with shelf life studies as detailed within Annex II of Regulation (EC) No 2073/2005. Further details on shelf life determination can be found from paragraph 43.

39. Compliance with the criterion for *Listeria monocytogenes* must be demonstrated as part of a routine sampling and testing regime carried out to verify that the FSMS is effective.

40. If testing detects the presence of *Listeria monocytogenes* in the milk at levels above the given criteria, the EA must be informed and sales of RDM must cease immediately. As with other unsatisfactory pathogen sample results, the FBO is also required to withdraw or where necessary recall any affected product on the market. Further detail on withdrawal and recall can be found towards the end of this document.

41. RDM can only be placed back on the market once corrective action has been taken and the FSMS has been re-validated to ensure it is operating effectively.

Corrective actions following unsatisfactory results

Best Practice

To enable adequate corrective action to be taken, it is important that the root cause of the problem is identified. To enable this, it is recommended that targeted sampling be carried out throughout the collection and bottling process to help identify the source of the contamination and where the problem lies, for example from the bulk tank and the final product container. Identifying and addressing the root cause of the failure will help to ensure that the same problem does not recur.

The EA may be able to offer advice on an appropriate sampling plan for your business, alternatively the assistance of a specialist in this area should be sought.

Once corrective action has been taken, to re-validate the FSMS, it is recommended at least two consecutive satisfactory results from samples of

different batches of milk are obtained. It is also recommended that the last verification sample is taken by the FSA.

It is strongly recommended that the FBO works closely with their local DHI in verifying compliance before any further RDM is placed on the market.

Verification testing by the FSA

42. Under Schedule 6 of The Food Safety and Hygiene (England) Regulations 2013 and The Food Hygiene (Wales) Regulations 2006, the FSA has a legal obligation to undertake verification sampling of raw cows' drinking milk (RCDM). Therefore, in addition to the FBO's own testing programme, FSA DHIs will review the sampling and test results and will test RCDM to verify compliance with microbiological standards during inspections. This verification sample will be tested for plate count, coliforms and pathogens.

43. A fee of £63 will be charged by the FSA to the FBO for each verification sample collected. This sampling will take place routinely twice per annum, however, the FSA can increase and decrease the frequency of testing should there be sufficient evidence to do so. The minimum frequency of testing will be once a year.

44. Sampling from species other than cows will be undertaken by LA officers.

Minimum durability and shelf life

45. Regulation (EU) 1169/2011, Article 24 requires that foods which, from a microbiological point of view, are highly perishable, are to be given a use by date. After the use by date a food shall be deemed to be unsafe in accordance with Article 14(2) to (5) of Regulation (EC) No 178/2002.

46. FBOs are responsible for establishing the appropriate date of minimum durability, which in the case of a ready-to-eat perishable product such as RDM would be a use-by date.

47. Regulation 3 of The Food Information Regulations 2014 and The Food Information (Wales) Regulations 2014, provides an exemption for reusable glass bottles meaning the bottle does not need to bear a use-by date.

Best Practice

FBOs are recommended to give consideration to the final use of the product by the consumer to enable the safe storage and use of RDM. Therefore, the shelf life of RDM still needs to be established and the FSA recommends information on durability be provided by the producer to the consumer via appropriate means. This could be by labelling the individual bottle, using signage at the point of sale or verbally to the consumer.

In addition to the use-by date, and statutory labelling requirements for RDM (see point 73 in this document), FBOs are recommended to provide the following information with the product;

- Storage conditions – RDM should be kept refrigerated below 5°C
- Storage conditions and shelf life if the RDM is frozen at home by the consumer on the day of purchase
- Instructions for safely defrosting the product within the refrigerator
- Shelf life of the RDM after it has been defrosted. This will depend on the number of days remaining on the original shelf life given when the product was frozen. The total shelf life given for chilled/defrosted milk must not exceed the original use-by date provided

48. The product must remain safe and retain its specific properties when properly stored.

49. How the use-by date is determined should be clearly detailed within the FBOs FSMS. It is the FBO's responsibility to ensure that RDM complies with the appropriate criteria. To do this the FBO must validate that the procedures within their FSMS are effective and verify they remain effective at regular intervals.

50. Regulation (EC) No 2073/2005 requires FBOs to ensure that food safety criteria applicable throughout the shelf-life of products, in this case *Listeria monocytogenes*, can be met under reasonably foreseeable conditions of distribution, storage and use. To this end it requires FBOs to conduct studies (set down in Annex II of the Regulation) to investigate product compliance throughout the shelf-life, particularly in the case of ready-to-eat foods that are able to support the growth of *Listeria monocytogenes.*

Best Practice

European Union industry guidance documents and UK industry guidance documents have been produced to help FBOs understand the range of different approaches available to help establish a safe product shelf-life in relation to *Listeria monocytogenes* and to demonstrate that products will comply with the *Listeria monocytogenes* criteria until the end of the assigned shelf-life.

One way to determine an accurate and reliable use-by date is by conducting appropriate shelf life studies, which may include consideration of product characteristics, the use of historical data including sampling and testing of end product, predictive mathematical modelling and laboratory studies such as challenge testing. These studies will allow the FBO to demonstrate that the product remains safe during its assigned shelf life.

It is recommended that FBOs seek expert advice when deciding how to determine the shelf life of their product. Advice on shelf-life studies is available from reputable microbiological testing laboratories. It is the responsibility of the FBO to ensure the use-by date on the product is valid and that the product will remain safe until this date.

Antibiotics

51. FBOs must have procedures in place to ensure that their RDM is not placed on the market if it contains antibiotic residues above the legal limit. Regulation (EC) No 37/2010 sets out the Maximum Residue Limits (MRLs) for individual veterinary medicines in foodstuffs of animal origin.

FBOs must keep a log of all medicines administered to animals. A system should be in place to ensure that the FBO can identify which animal(s) have been treated so that they can ensure their milk is disposed of appropriately and not added to the bulk tank.

Best Practice

It is best practice for the FBO to document any procedures they implement to identify animals that are undergoing treatment within their medical records or FSMS. This should detail how they will identify which animals

are undergoing treatment and how they will ensure that the milk does not enter the food chain.

52. The milk first purchaser will carry out this testing and report any results indicating chemical residues to the FBO and the FSA. Once notified the DHI will visit your premises and assess procedures.

53. If FBOs are only selling RDM and do not sell to a first purchaser, they will need to undertake such testing themselves and demonstrate compliance with the criteria.

54. Different drugs will have different withdrawal periods, therefore RDM from treated animals will need to be kept out of the food chain for differing lengths of time. FBOs must ensure that they comply with specific withdrawal periods.

Best Practice

The FBO should seek advice from their vet and/or the DHI for their specific situation. Further advice and information, including on testing milk through the production chain can be found in Milk hygiene and antibiotic residues guidance.

Tuberculosis status

55. In accordance with Regulation (EC) No 853/2004, Annex III, Section IX, raw milk and colostrum must come from animals with an official free status for Tuberculosis (TB) and Brucellosis (BR) unless the milk is heat treated to show a negative reaction to the alkaline phosphatase test. It must never come from animals infected by these diseases. Therefore, RDM for direct human consumption must come from a herd that is officially TB free (OTF) and officially BR free.

56. If the FBO suspects that an animal may be affected by any notifiable disease, including TB or BR, they are legally obliged to report this to the Animal and Plant Health Agency (APHA). The animal must be isolated until the presence of disease is confirmed. More details regarding notifiable diseases and how to report them can be found online.

57. APHA carry out TB testing on cattle and buffalo farms producing RDM at least on an annual basis. Other milk-producing species are not routinely tested by APHA, except goat herds that are co-located or share a boundary with a cattle farm affected by a lesion or culture positive TB incident ('breakdown'), and/or if *Mycobacterium bovis* infection has been confirmed in a goat or sheep flock. APHA, however, do not confer OTF status to herds of any species other than bovines (i.e. cattle, farmed buffalo and farmed bison).

58. Further specific information about Brucellosis and how to spot it can be found online.

59. If your herd loses its OTF statusfor whatever reason (including a TB breakdown, a notification of TB in carcases of animals during commercial slaughter, an overdue TB test etc.), APHA will notify the FSA, the relevant LA and the FBO. This notification should state that all the raw milk must be heat treated and that it must not be consumed in its raw state until the herd has regained its OTF status. The DHI will contact you or visit your premises to ensure that RDM sales have stopped. Enforcement action will be taken if it is found that RDM sales have continued in breach of APHA notification and the relevant food hygiene legislation.

60. APHA will serve a notice on the FBO that will detail exactly what restrictions are placed on the herd. To determine this, APHA will carry out an assessment to establish whether individual animals or the whole herd needs to be under TB restriction. For instance, if one or more animals from the herd has/have given a positive reaction to a statutory TB test - for example animals that are deemed TB reactors - TB restrictions will apply to the whole herd and no milk from these individual TB reactor animals can enter the food chain – see paragraph 61. Until the TB herd restrictions have been lifted and the OTF status restored, milk from other animals in the herd – those not deemed a TB reactor – can enter the food chain providing it is heat treated – see paragraph 55. By contrast, if one or more animals from an OTF herd give an inconclusive reaction to the tuberculin skin test, without any concurrent test reactors, APHA will only place the individual animal(s) under movement restrictions pending re-testing. In this case, the affected herd will normally be allowed to retain its OTF status. Milk from inconclusive reactors may still go for human consumption, provided it is heat treated before it is sold.

61. Milk from animals showing a positive reaction to an official test for TB must not be used for human consumption even when heat treated and milk from these animals must be withheld from the bulk tank. The Environment Agency should be contacted for further information about disposal of reactor milk.

Best Practice

It is recommended that you do not feed milk from reactor animals to calves or other livestock on your own holding. If it is used, reactor milk may only be given to animals on the same farm after suitable heat treatment.

62. Animals showing a positive reaction to official tests for TB or BR must be kept in isolation. To prevent the spread of disease, isolation facilities should have separate drainage and airspace. To prevent milk from TB/BR free animals becoming contaminated, reactor animals awaiting removal from the farm must be milked last and the milking equipment subsequently cleaned with a full sanitising wash routine. The milk must be disposed of appropriately.

63. Milk from animals in a reactor herd that do not show a positive reaction to the test for TB must be heat treated before being sold for human consumption. The FBO or person in charge at the primary production holding must ensure that they or their milk purchaser puts all milk through a suitable heat treatment.

64. Milk from inconclusive reactors to the tuberculin skin test awaiting a re-test may still go for human consumption, provided it is heat treated - to show a negative reaction to an alkaline phosphatase test - before it is sold, as detailed above.

65. Raw milk from non-TB reactor animals in herds that have lost their OTF status cannot be used as an ingredient in raw milk products, such as cream or cheese, unless it is heat treated to show a negative reaction to an alkaline phosphatase test. Raw milk from TB reactor animals must not be supplied to other businesses that will be producing raw milk products.

66. When subsequent test results are negative and the herd has regained its OTF status, APHA will provide confirmation of this to the FBO, LA and FSA.

67. Once the FSA have received notification of the restored OTF herd status from APHA, the DHI will visit the premises. In order to meet their legal obligations, the FBO will need to demonstrate that their FSMS remains effective and provide test results to demonstrate verification of this.

68. Free advice and information about how farmers can mitigate the risk of TB affecting their herds can be obtained from the TB Advisory Service (TBAS) for herds in the high risk and edge areas of England. Further advice and information can also be found in the TB Hub.

Water supply requirements

69. All water used in the parlour, milk storage room and milk filling areas must be potable/wholesome or clean.

70. Potable water – also known as wholesome water - is defined with Regulation (EC) No 852/2004, Article 2 as water that meets the minimum requirements of Council Directive 98/83/EC. This is enforced with England and Wales by The Water Supply (Water Quality) Regulations 2016 and The Water Supply (Water Quality) Regulations 2018.

71. Clean water is defined by Regulation (EC) 852/2004, Article 2 as clean seawater or fresh water of a similar quality. Clean seawater is defined as natural, purified or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food. Further guidance about when the use of clean water is suitable can be found within FSA's Guidance for Enforcement Authorities on the Use of Private Water Supplies in Primary Production.

72. For water to be classed as potable or wholesome and be suitable for use in food production premises, *E. coli* or Enterococci must be absent within a 100ml sample when taken from the FBOs tap from which water for business use is drawn.

Best Practice

If mains water is used, it can be assumed that the water supply is safe and in compliance with these requirements. However, it is recommended that the water supply be tested at point of delivery annually to ensure that the pipework and equipment used to deliver and transport water on your premises is in a sound state and is not a source for contamination.

If a private water supply is used, the FBO will need to consider how they demonstrate that the above requirements are being met. While it is up to the FBO to determine how they will demonstrate compliance with this requirement, it is recommended that private water supplies are tested on a routine basis for colony count and pathogens. The frequency of such testing should be risk based and determined within the FSMS.

Further guidance on the use of private water supplies can be found in the FSA's Guidance for Enforcement Authorities on the Use of Private Water Supplies in Primary Production.

Labelling of raw drinking milk

73. Even when good hygiene management practices and procedures are in place with a satisfactory FSMS, RDM may still be harmful to health. It is for this reason that RDM for direct human consumption as a ready-to-eat product must clearly carry a health warning, as required by The Food Hygiene and Safety (England) Regulations 2013 and The Food Hygiene (Wales) Regulations 2006, Schedules 6.

74. This is applicable to RDM produced from all species, with the exception of buffalo, and is as follows:

England:

Container: "This milk has not been heat-treated and may therefore contain organisms harmful to health." and/or

Not prepacked: "Milk supplied in this establishment has not been heat-treated and may therefore contain organisms harmful to health."

Wales:

In Wales, in addition to the wording required in England as above, the health warning must also include, either on the container or on the notice at the point of sale, the statement below.

"The Food Standards Agency strongly advises that it should not be consumed by children, pregnant women, older people or those who are unwell or have chronic illness."

Best Practice

While this additional statement is only a legal requirement in Wales, it is recommended that all FBOs label their product with this additional warning.

75. For RDM which is sold in a pre-packed container, the health warning must appear on a label attached to the container in which that milk is placed on the market.

76. In the case of any RDM which is not prepacked and is placed on the market at a farm catering operation, such as a farm shop or bed and breakfast, the health warning must appear on a ticket or notice that is readily discernible by an intending purchaser at the place where the consumer chooses that milk.

77. Where vending machines are used to sell milk within the curtilage of the production holding, the health warning must be clearly displayed to the purchaser at the point of purchase.

78. Regulation (EC) No 853/2004, Annex III, Section 9, Chapter IV also requires that raw milk intended for direct human consumption, meaning RDM, must be labelled with the words 'raw milk'. This applies to all RDM placed on the market with the exception of RDM provided in reusable glass bottles, for example via a roundsman.

79. When RDM is being pre-packed at the farm before being offered for sale from the farm to the final consumer – i.e. either sold direct or via an internet sale – or if RDM is packed to order, the mandatory labelling requirements in Article 9 of Regulation (EU) 1169/2011 do not apply.

80. LAs are responsible for enforcement of food labelling requirements and any advice relating to other food standards matters such as labelling and weights and measures requirements should be directed to your LA. General guidance on food labelling of pre-packed and non-pre-packed foods can be found on the FSA website.

81. Although consumption of RDM is not widespread some consumers believe it possesses particular health properties in addition to its standard natural components. There are currently no scientifically proven health benefits linked to the consumption of raw milk in England and Wales, therefore claiming or advertising such benefits could prove misleading and may result in enforcement action being taken in accordance with Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

Withdrawal/Recall procedures

82. Article 19 of Regulation (EC) No 178/2002 requires an FBO to withdraw and when necessary recall food from the market if they consider or have reason to believe

that the food is not in compliance with the food safety requirements. The FBO is also required to inform the EA.

83. This means that as a result of a food incident, for example when a food product is found to be contaminated or associated with an outbreak of illness, it may have to be withdrawn or recalled from the market.

- a withdrawal is when unsafe food is removed from the supply chain before it has reached consumers.
- a recall is when unsafe food is removed from the supply chain and consumers are advised to take appropriate action, for example to return or dispose of the unsafe food.

84. FBOs are required to have a documented procedure detailing their process for withdrawal and/or recall of product which is deemed unsafe for human consumption.

85. This documented procedure would depend on how this product is sold and marketed, such as sales through the internet, via a distributor, social media advertising or a website. This should be addressed on a case by case scenario, commensurate with the size and nature of the sale. Your recall procedures should be discussed with the EA.

Best Practice

An example of a food withdrawal/recall plan may include procedures and documentation such as:

- list of team members involved in implementing the plan
- definition of team member roles and responsibilities
- contact details
- risk assessment and notification procedures
- communication templates
- food incident log
- review and testing procedures

A way of ensuring that suitable systems and procedures are in place to deal with a food safety incident is to carry out a periodic review and testing of the business's plan and procedures. FBOs should review a food withdrawal/recall plan and its procedures on an annual basis. This could

include an incident mock exercise, involving business customers (including retailers for species other than cows and distributors), as it is easier to challenge and audit the plan following a mock exercise than during a real-life situation.

Further guidance on this matter can be found within Guidance on Food Traceability, Withdrawals and Recalls within the UK Food Industry.

Review

86. The FSA aims to keep all guidance material up to date and undertakes regular reviews of guidance material to ensure that material is still relevant. The next scheduled review date for this guidance is February 2021.

87. The FSA welcomes user feedback on guidance, including reports of any broken links to reference material or other content that may require updating. Please use the contact details below.

Contacts

88. Enquiries around the implementation of procedures detailed within this guidance may wish to seek the advice of the FSAs Dairy Operations at the following contact:

Email: DairyOps@food.gov.uk

89. Questions regarding this guidance document should be posed to the FSA at either of the following contacts:

Email: PPfoodhygiene@food.gov.uk

Email: Food.Policy.Wales@food.gov.uk

Annex I: Relevant legislation and guidance

This annex lists all relevant legislation and guidance that has been referenced in the text of this document.

EU Legislation

Regulation (EC) No 852/2004 on the hygiene of foodstuffs

Regulation (EC) No 853/2004 laying down specific hygiene rules for products of animal origin

Official Controls Regulation (EU) 2017/625

Commission Implementing Regulation (EU) 2019/627

Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

Regulation (EC) No 178/2002 on food safety, traceability and product recall / withdrawal

Regulation (EC) No 1169/2011 on the provision of food information to consumers

Council Directive 98/83/EC on the quality of water intended for human consumption

Council Directive 2006/42/EC on machinery, and amending Directive 95/16/EC

Commission Regulation EU (No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin

National Legislation

The Food Safety and Hygiene (England) Regulations 2013

The Food Hygiene (Wales) Regulations 2006

The Food Information Regulations 2014

The Food Information (Wales) Regulations 2014

The General Food Regulations 2004

The Private Water Supplies (England) Regulations 2018

The Private Water Supplies (Wales) Regulations 2017

The Water Supply (Water Quality) Regulations 2016

The Water Supply (Water Quality) Regulations 2018

General Guidance

FSA, Safer food, better business

FSA, Staff training guidance

Word Health Organization, Good washing hands technique

FSA, HACCP

Guidance Notes for food business operators on food incidents

Health and Safety Executive, Control of substances hazardous to health catering specific

Health and Safety Executive, Storing chemical products (small scale)

Health and Safety Executive, Diluting chemical concentrates

Guidance on Food Traceability, withdrawals and recalls within the UK Food Industry

Guidance for Enforcement Authorities on the Use of Private Water Supplies in Primary Production.

A Practical Guide for Milk Producers

Brucellosis: How to spot and report the disease

Notifiable diseases in animals

Guidance on Packaging and Labelling

Information and guidance on the testing of milk for antibiotic residues

Shelf life of ready to eat food in relation to L. monocytogenes – Guidance for food business operators

Guidance document on Listeria monocytogenes shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Annex II: Table showing split of enforcement and official controls between the FSA and LA

Controls	Enforcing authority
Enforcement of food safety and hygiene controls at primary production dairy holdings for all species (before pasteurisation).	FSA are the enforcing authority
Enforcement of official controls for **RCDM for sale** direct to the consumer.	FSA are the enforcing authority
Delivery of verification **sampling programme of RCDM** under Schedule 6 (TVC's/Coliforms).	FSA are the enforcing authority
Delivery of verification **sampling programme of RDM** from species other than cows, under Schedule 6, (sheep, goats etc).	LA are the enforcing authority
Enforcement of the **health warning** label required at the point of sale on **RCDM** for sale direct to the final consumer.	FSA are the enforcing authority
Enforcement of **the health warning** label required at the point of sale on **RDM** of species other than cows.	LA are the enforcing authority[1]
Inspections and enforcement of bottling wrapping and packaging processes for RDM (all species)	LA are the enforcing authority[1]
Enforcement **of sales routes controls for RCDM** direct to the final consumer	FSA are the enforcing authority
Further processing into a dairy product i.e. cheese, yoghurt, ice cream. Approvable activities	LA are the enforcing authority

[1] LA may refer to District Council or County Council in these cases depending on which authority has responsibility for the enforcement of labelling legislation

Annex III: Raw cows drinking milk sales routes

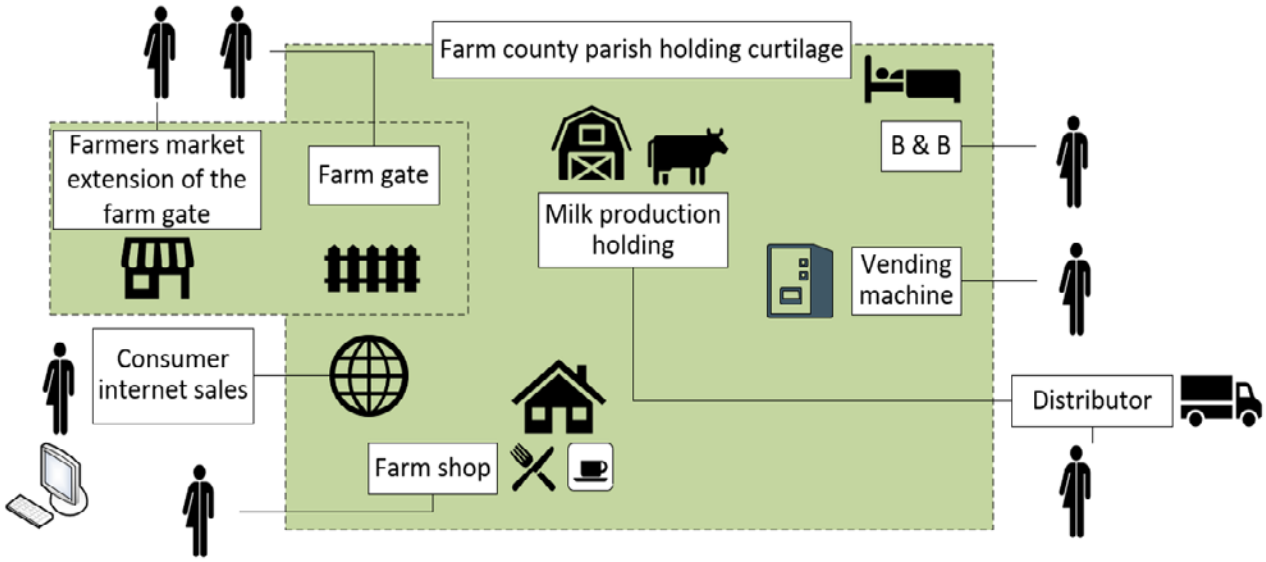

Image caption: Permitted marketing routes for the sales of raw cows drinking milk to the final consumer for human consumption

The image above demonstrates the ways in which a milk production holding producing raw cows drinking milk can sell their milk to the final consumer. These are as follows.

- To a distributor who is selling directly to the final consumer
- From a farm shop within the curtilage of the holding that is selling directly to the final consumer
- From a vending machine within the curtilage of the holding that is selling directly to the final consumer
- From a bed and breakfast within the curtilage of the holding that is selling directly to the final consumer
- Via internet sales from the production holding direct to the final consumer
- From the farm gate direct to the final consumer
- A stall at a farmer's market is considered an extension of the farm gate so a stall can sell raw drinking milk to the final consumer

Annex IV: Glossary

Coliforms – Bacteria that are present in the digestive tracts of animals, including humans, and are found in their wastes. Also found in plant and soil material.

Contamination – The presence or introduction of a hazard i.e. soiling, bacteria, chemicals, antibiotics.

Direct for human consumption – A food that is intended to be consumed directly by the consumer in the state in which it was obtained, without further processing or treatment.

Food Business Operator (FBO) – Food business operator. Regulation (EC) No 178/2002 defines 'food business operator' as the natural or legal person(s) responsible for ensuring that the requirements of food law are met within the food business under their control. Examples include a farmer, butcher or restaurant owner.

Food safety criterion – A criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market.

Geometric average – The average (or mean) of a typical value of numbers found by using the product of their values and not the sum (multiplication of the numbers and then take the root of this number e.g. square if two, cube if three).

Hazard – A biological, chemical or physical agent in food with the potential to cause harm to the consumer's health.

Inspection – The examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and welfare rules.

Mains water supply – Water supplied by the public water supply system.

Maximum residue limit (MRL) – Maximum concentration of residue resulting from the use of a veterinary medicinal product which recognised as acceptable in or on food. Full definition as per Council Regulation (EEC) No 2377/90, Article 1. NB Advice may also be sought on the VMD website.

Milk first purchaser – An FBO who purchases milk wholesale from dairy farms/producers to treat or process within its business.

Monitoring – A pre-arranged programme of checks (observations or measurements) of critical and/or 'legal' limits to check whether control measures are in danger of failing and which determine the need to take corrective actions.

Pathogens – Microorganisms such as harmful bacteria and viruses that cause disease.

Plate count – Also known as Total Viable Count (TVC), giving a quantitative estimate of the concentration of microorganisms such as bacteria, yeast or mould spores in a sample. This count indicates the number of colony forming units (cfu) per g/ml of the sample.

Potable water – Water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

Private water supply – Any water supply that does not originate from the public water mains.

Raw drinking milk (RDM) – Milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40ºC or undergone any treatment that has an equivalent effect. The intention is for the milk to be drunk directly.

Ready-to-eat – Food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate, or reduce to an acceptable level, micro-organisms of concern.

Recall – When customers are asked to return/dispose of a food product. This may be needed if there is a serious issue with the food. Information on the control of food incidents can be found on the FSA's incidents webpage.

Risk – The chance or probability that a person will be harmed or experience an adverse health effect if exposed to a hazard.

Sampling – Taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health rules.

Shelf life – The period during which the product maintains its microbiological safety and suitability at a specified storage temperature and, where appropriate, under specified storage and handling conditions.

Somatic Cell Count (SCC) – The main indicator of milk quality and **is quantified as the** *number of cells per ml* **of milk.**

Validation checks – Before implementing a FSMS, the contents of the plan must be validated. This is to make sure the system will lead to safe food being produced. The focus is to ensure that the hazards identified are complete, correct and that suitable controls are in place.

Verification – This means performing tests or checks, checking that procedures are being adhered to and reviewing the FSMS to ensure that the food being produced is safe.

Withdrawal – The process of withdrawing a product from market. This may need to happen if there is a serious issue with a food product. See FSA Food incidents page for more information.

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