Registration guidance document for raw drinking milk producers in England and Wales

Publication Date: 23/01/2019

Last Reviewed:

Revision history

Revised	Purpose of revision and paragraph number	Revised by
23/01/2019	Original document production	C Thompson

Summary

Intended audience:	• Manufacturers and processors
Which UK nations does this cover?	England and Wales
Purpose:	This document is intended to provide guidance on both legal requirements and expectations on the processes and systems needed to gain registration to supply Raw Drinking Milk direct for human consumption
Legal status:	This document provides advice on policy expectations as well as regulatory guidance on legal requirements
Key words	• Dairy products • Food law, monitoring and controls • Hygiene and food safety • Labelling, composition and lot marking of food • Nutrition and health claims
Review date	01/02/2020

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Introduction

1. In recent years, there has been a growing demand for the consumption of raw unpasteurised milk that has not undergone any form of heat treatment sufficient to kill harmful bacteria that may be present in the raw product.

2. Although consumption of raw drinking milk 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 mis-leading.

3. The lack of pasteurisation increases the risk of pathogens obtained during production being carried through to the product sold to the final consumer. It is for this reason that raw drinking milk as a ready-to-eat product must clearly carry the health warning "*This milk has not been heat-treated and may therefore contain organisms harmful to health"*

4. The Food Standards Agency (FSA) therefore advises that consumers who have a weakened immune system and are particularly vulnerable to food poisoning should not consume unpasteurised milk, cream or products made from raw milk which have not gone through a thermal process to kill bacteria (e.g. pasteurisation). Vulnerable groups include children, pregnant women, older people and those who are unwell, have chronic illness and/or are immunocompromised.

5. Sales of raw drinking milk direct for human consumption are restricted in England and Wales. Further details around these sales restrictions.

   There is also information included at Annex B.

6. FSA Dairy Operations carry out official controls (hygiene inspections and sampling) at dairy production holdings supplying raw drinking milk direct to the final consumer.

Intended audience

7. This guidance is intended to assist current producers and anyone who is considering becoming a producer of “Raw Drinking Milk” (RDM) intended for supply direct to the consumer.

Purpose of guidance

8. This document is intended for food business operators (FBO’s) planning to supply raw drinking milk direct for human consumption. Some provisions for raw drinking milk produced from species other than cows are subject to alternative controls, further details of which can be found later in this document. The purpose of the guidance is to assist RDM producers in understanding the specific food hygiene requirements relating to the registration, production and sale of raw drinking milk in England and Wales. This document has been produced to provide an overview of the requirements of the legislation and FSA policy on the subject and should be read in conjunction with the legislation itself. The guidance should not be taken as an authoritative statement of interpretation of the law, as only the courts have this power. References to legislation in this guidance mean the legislation in its amended form.

Legal status of guidance

9. This guidance note has been produced to provide advice on the legal requirements of:

- *Regulation (EC) No. 178/2002 General Food Safety Law*
- *Regulation (EC) No. 882/2004 General Rules for Official Controls*
- *Regulation (EC) No. 852/2004 General Rules on Hygiene*
- *Regulation (EC) No. 853/2004 Hygiene Rules for Food of Animal Origin*
- *The Food Safety & Hygiene (England) Regulations 2013*
- *The Food Hygiene (Wales) Regulations 2006*
- *Regulation (EC) No. 2073/2005 Microbiological Criteria of Foodstuffs*

10. Businesses with specific queries may wish to seek the advice of their local Dairy Hygiene Inspector. For queries on approval and the further processing of dairy products, businesses should contact the trading standards / environmental health department of the local authority of the area where their business is located.

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.

Registration

12. All farms producing raw drinking milk must notify and register with the FSA's Registrations and Approvals team [contact details below] and request a registration package, prior to the production and sale of raw drinking milk. This document explains the procedure you would need to follow to gain such registration before you can legally produce and sell RDM.

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

Requirements for Raw Drinking Milk

14. As the Central Competent Authority responsible for registration of RDM producers, the following section sets out the standards that the FSA will expect producers to comply with in order to be registered for RDM production and sale.

15. To comply with all of the relevant safety and hygiene regulations, farmers supplying raw drinking milk direct for human consumption should ensure that their milk meets the criteria contained within.

16. Schedule 6 of The Food Safety and Hygiene Regulations (England) 2013 and The Food Hygiene (Wales) Regulations 2006, which specify that raw milk must meet the following standards

    a. Plate count at 30°C (cfu per ml) ≤ 20,000

    b. Coliforms (cfu per ml) < 100

17. Producers 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 the “use-by” date. This durability mark must provide assurance through a validated scientific method, such as historical test date if available or through conducting shelf life studies that the milk continues to meet the microbiological standards above, as well as those contained within the EU microbiological criteria regulations (Regulation (EC) 2073/2005 – see below).

18. The product must continue to meet the legislative criteria and retain acceptable organoleptic (taste, texture, smell, appearance), microbiological and chemical characteristics. Advice on shelf-life studies is available from reputable microbiological testing laboratories. Regulation (EU) 1169/2011 sets out the provisions for food information to consumers and defines the “date of minimum durability” of a food as the date until which the food retains its specific properties when properly stored.

19. Article 24 of Regulation (EU) 1169/2011 sets out the minimum durability requirements for food and requires that in the case of foods which, from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the ‘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.

20. Regulation (EC) No. 2073/2005 Microbiological Criteria of Foodstuffs 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 applies). Producers must ensure that RDM complies with the appropriate criterion throughout the shelf-life of the product and are obliged to withdraw product batches from the market if this criterion is not met (Article 19 of Regulation (EC) 178/2002). Producers can demonstrate compliance by

carrying out testing against the appropriate criterion when validating or verifying that their food safety management system is functioning correctly. Producers should therefore decide the appropriate testing frequency in the context of their food safety management system. It is recommended that the frequency of this testing matches that of other tests being undertaken by the producer.

21. Where RDM has a shelf-life of less than 5 days (up to 4 days) it may be assumed that *Listeria Monocytogenes* will not grow and Annex I, Chapter 1, point 1.3 applies. In this case producers should demonstrate compliance with the limit of 100 colony forming units (cfu) per ml.

22. In order to allocate a longer shelf-life, producers need to demonstrate that *Listeria Monocytogenes* will not exceed 100 cfu per ml throughout the shelf life of the product and criterion 1.2a applies. This may be demonstrated by historical test data, if available, or by carrying out shelf life studies.

23. If producers cannot satisfy the FSA that the level of *Listeria monocytogenes* will remain below 100 cfu per ml throughout the desired shelf life, the product shelf-life should be limited to 4 days or criterion 1.2 b applies. This requires the producer to demonstrate *Listeria monocytogenes* is absent at the end of production (e.g. bottling).

24. Other standards for raw drinking milk include:

Microbiological safety

25. Regulation (EC) No 178/2002, Article 14 requires that food is not placed on the market if it is unsafe, and therefore, milk should not contain harmful bacteria. Sampling has found that the following harmful bacteria / pathogens are also associated with and may be present in raw milk:

    a. Salmonella spp 0 cfu/25ml

    b. Campylobacter spp 0 cfu/25ml

    c. Shiga Toxin E.Coli 0 cfu/25ml

    d. Coagulase positive staphylococci 20cfu/ml

Somatic Cell Count (SCC) and Plate Count (at 30C)

26. All milk produced and sold must meet the requirements for somatic cell count and plate count as outlined in Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, Part III, point 3 which requires that:

Raw cows milk:

a. SCC: 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)

b. 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:

c. SCC: There is no legal requirement to sample for SCC

d. Plate Count: The legislation splits the requirement into 2 different criteria depending on the intended use:

   i. Milk intending to produce heat treated products: The rolling geometric average must be equal or below 1,500,000 per ml (over a two-month period with at least 2 samples per month)

   ii. Milk intended to produce non-heat-treated products: The rolling geometric average must be equal or below 500,000 per ml (over a two-month period, with at least 2 samples per month)

Antibiotics.

27. FBO's must have procedures in place to ensure that their raw drinking milk 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 (MRL's) for individual veterinary medicines in foodstuffs of animal origin.

Tuberculosis (TB) / Brucellosis (BR) status:

28. Raw milk direct for human consumption must come from a herd that his officially TB free and either BR free or officially BR free.

Water supply requirements.

29. All water used in the parlour, milk storage room and milk filling areas must be potable or clean and the following microbiological standards for water are expected:

    a. Colony count @ 22C No abnormal change (guideline <100/ml)

    b. Colony count @ 37C No abnormal change (guideline <10/ml)

    c. Coliforms 0/100ml

    d. Escherichia coli 0/100ml

    e. Enterococci 0/100ml

    f. Clostridium perfringens 0/100ml

30. Potable or clean water must not contain any harmful bacteria (pathogens) and results of water samples for harmful bacteria must demonstrate that there are “none present in 100ml” for the water supply to be considered acceptable for use.

Requirements for testing

31. FBOs supplying raw drinking milk direct for human consumption will need to consider how they will demonstrate that the hygienic controls they have in place via their food safety management systems (FSMS) are effective and how they can prove that their product meets the requirements mentioned above. The FSA considers that the best way to verify these systems is by undertaking microbiological testing.

32. FBO’s will be expected to provide one full set of test results (plate count, coliforms and pathogens) for the milk and the water supply which demonstrate the above requirements have been met for each month during 2 consecutive

months before raw milk supply is allowed to commence. Thereafter the frequency of testing is as outlined below:

33. Frequency of testing will differ depending on the nature and style of the business it is applicable to. FBO's will be required to refer to the FSMS and the assessment of the risks associated to their production systems to justify the frequency at which they decide to test their product. The points below are our policy guidelines for testing.

    a. **Raw milk**: Plate Count and Coliform

    b. **Raw milk**: Pathogens (Salmonella spp, Campylobacter spp, STEC)

    c. ***Listeria Monocytogenes***: Requirements for testing are covered in the shelf life section earlier in this document

34. In addition to this FBO's will be asked to provide assurance that the water that they use is safe, the only way to do this is by testing the water. The frequency of the verification testing of the water should again be based on risk.

35. If testing identifies the presence of harmful bacteria (pathogens) in the milk or water, **sales of raw drinking milk must cease immediately**. The root cause of the problem must be identified and corrective action taken to prevent its reoccurrence. Further testing should be undertaken to verify that the corrective action taken has been effective and the FSA must be kept informed. Supply must not resume until at least 2 consecutive satisfactory results taken from different batches of milk are obtained with the final sample being a verification sample taken by the FSA.

36. If plate count and/or coliform testing indicates levels greater that the legal requirements, we recommend that sales cease. The FBO should take steps to investigate the cause of the problem and take corrective action to prevent reoccurrence. Further sampling should be undertaken to verify if the corrective action taken has been effective. Should this testing show results that continue to fall short of the legal standards required, sales of raw milk should cease, further detailed investigation should take place and a continued cessation of sales should continue until satisfactory results are achieved.

37. **Please note:** Additional somatic cell count, plate count and antibiotic testing is not required if the majority of milk is still purchased and tested by milk purchaser. The milk purchaser will carry out this testing and report results to the FBO and the FSA. Any results indicating the presence of antibiotic residues and/or high somatic cell counts/plate counts should be reported to the FSA by the milk purchaser. If FBO's are only selling RDM and do not sell to a milk purchaser, they will need to consider how they are going to demonstrate compliance with the criteria and undertake such testing themselves.

Reporting results to FSA and verification testing by FSA.

38. All results that do not meet the required standards must be reported to the FSA as soon as these results are available. FSA Dairy Hygiene Inspectors (DHI) will check all test results during inspections. In addition to the FBO's own testing programme, the FSA has a legal obligation to undertake verification sampling. DHIs will carry out verification sampling and testing of RCDM to verify compliance with microbiological standards. A fee of £63 will be charged by the FSA to the FBO for each sample collected. Routinely this sampling will take place twice per year, however the FSA reserves the right to increase this sampling frequency should there be any evidence to demonstrate that this is necessary. Alternatively, the sampling frequency may be decreased should there be evidence to demonstrate that this is possible (i.e. the producer is able to provide evidence of historic compliance with the micro criteria demonstrating that FBOs own systems and verification sampling are effective. This will require a minimum of 6 consecutive months of satisfactory results). The minimum frequency of testing will be once per year.

39. **Note; Sampling from species other than cows will be undertaken by Local Authority (LA) officers**.

40.

Labelling of Raw Drinking Milk

41. Raw milk must be labelled 'Raw milk' (as required by Regulation (EC) No 853/2004). Schedule 6 of The Food Safety and Hygiene (England|) Regulations 2013 or The Food Hygiene (Wales) Regulations 2006 requires that a health warning must be provided to inform consumers that the milk has not been pasteurised and may contain organisms harmful to health. This is

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

a. England:

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

43. NOT PREPACKED: *"Milk supplied in this establishment has not been heat-treated and may therefore contain organisms harmful to health."*

a. Wales:

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

45. NOT PREPACKED: *"Milk supplied in this establishment has not been heat-treated and may therefore contain organisms harmful to health."* And

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

47. For milk 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 sold. In the case of any raw milk which is not prepacked and is sold at a farm catering operation, e.g. a farm shop or B&B, the health warning must appear on a ticket or notice that is readily discernible by an intending purchaser at the place where the purchaser chooses that milk. Where vending machines are used, the health warning must be clearly displayed to the purchaser at the point of purchase.

48. Other aspects of food labelling are the jurisdiction of the Local Authority and any advice required on to ensure compliance with other food standards, labelling and weights and measures requirements should be directed to the Environmental Health / Trading Standards departments at your Local Authority. As stated in paragraph 17, RDM is a perishable product and Regulation (EU) 1169/2011, Article 24 requires that a "use-by" date determined through shelf life testing is applied to the labels / product. There is an exception for reusable bottles (i.e. the bottle does not need to bear the durability marking), but information on durability would still need to be provided by the producer to the

consumer via alternatives means. The shelf life of the product would need to be defined. The FBO must have an appropriate labelling system in place that complies with all legal requirements.

Food Safety Management Systems (FSMS)

49. Regulation (EC) No. 178/2002 General Food Law places the responsibility for the production and supply of safe food, such as raw drinking milk, solely with the FBO. As the supplier of the raw drinking milk direct for human consumption, the FBO has the responsibility for ensuring that their milk does not present a health risk to consumers and they must demonstrate to the competent authority what measures have been taken to ensure they have in place a FSMS which is designed to identify and control all relevant hazards associated with the production of raw drinking milk.

50. Having a documented FSMS will help FBO's to demonstrate how they comply with food safety and hygiene legislation and control food safety hazards. FBO's should consider the following 7 steps when designing their food safety management plan:

    a. Conduct a hazard analysis. (Identify what could go wrong i.e. the hazards)

    b. Identify where controls should be in place

    c. Set critical limits at each control. (Decide the parameters that will dictate acceptability against unacceptability)

    d. Establish a monitoring system for each. (Carry out checks to determine that the control is working)

    e. Establish corrective action. (Decide what to do when it goes out of control – how to put it right and prevent it occurring again)

    f. Establish verification procedures to determine if the system is working effectively. (Prove that the FSMS is working)

    g. Establish documentation and record keeping.

51. Examples of documentation that can be used as part of your FSMS can be found at Annex A. This is not an exhaustive list and the dairy hygiene inspector may discuss other options with you at the time of inspection.

Withdraw/recall procedures.

52. FBOs will be required to have a documented procedure to withdraw and/or recall product which is deemed unsafe for human consumption, as required by Article 19 of Regulation (EC) 178/2002. This documented procedure would depend on how this product is marketed (e.g. internet sales, distributor, social media advertising, website etc).

Registration inspection of dairy production holdings.

53. The DHI will carry out a registration visit once the documentation provided by the FBO (as above) has been deemed satisfactory. The aim of this visit is to assess the following:

    a. Implementation of the FSMS, cleaning protocols, shelf life determination, veterinary drug control system, identification of cows not being milked for human consumption, etc;

    b. Assessment of the labelling of RDM and proposed sales routes;

    c. General farm hygiene conditions, hygiene facilities, type of parlour/milking, milking operations, animal cleanliness, etc; and

    d. General management of the farm, confidence in management, etc.

54. **Please note:** bottling operations are currently under LA's official controls and the local EHO would need to be contacted to arrange a visit to assess the bottling/filling operation.

Publication of compliance category.

55. Registration details of all Raw Drinking Milk establishments together with their compliance rating following the most recent dairy hygiene inspection are published on the FSA website.

References

Regulation (EC) No. 178/2002 General Food Law

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002R0178-20140630&qid=1478866165051&from=EN

Regulation (EC) No. 882/2004 General Rules for Official Controls

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0882 20140630&qid=1478866265644&from=EN
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0882&qid=1539678432266&from=EN

Regulation (EC) No. 852/2004 General Rules on Hygiene - *sets out the general hygiene rules to be applied by all food businesses to protect customers.*

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0852-20090420&qid=1478867055283&from=EN

Regulation (EC) No. 853/2004 Hygiene Rules for Food of Animal Origin - *lays down specific hygiene rules for food of animal origin including milk.*

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0853-20160401&qid=1478867135454&from=EN

The Food Safety and Hygiene Regulations (England) 2013 or The Food Hygiene Regulations (Wales) 2006 – *these regulations make provision for the execution and enforcement of EU food hygiene regulations in England and Wales and places restrictions on the sale of raw drinking milk intended for direct human consumption.*
http://www.legislation.gov.uk/uksi/2013/2996/contents/made

http://www.legislation.gov.uk/wsi/2006/31/contents/made

Regulation (EC) No. 2073/2005 Microbiological Criteria of Foodstuffs

56. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005R2073-20140601&qid=1439307127534&from=EN

Review

57. The FSA aims to keep all guidance material up to date and undertakes regular reviews of this material to ensure it is still relevant. The next scheduled review date for this guidance is intended to be on or around 04/02/2020 or sooner if deemed necessary.

58. 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

Dairy Operational Lead. Colin Thompson. 07738199043.
Colin.thompson@food.gov.uk

Lead Dairy Hygiene Inspector. Charles Boundy. 07881281204.
Charles.boundy@food.gov.uk

Annex A: Model documentation

59. Annex A gives examples of the types of documented checks that should be considered for use in the FSMS, this list is not exhaustive and other options can be suggested by the DHI as part of their inspections.

Veterinary Records

You can use this sheet to write down and record the use of veterinary medicines within your herd; it is important that these records are kept up to date and are accurate. Entries should be made within 72 hours of treatment

Name of veterinary medicine	First date of use	Identity of animal/group treated	Person administering medicine	Date treatment finished	Withdrawal period end date*			Total quantity of medicine used	Batch No.	Source of medicine
					Milk	Meat	Other			
Example	01/5/12	100056	A. Herdsman	08/5/12	15/5/12	20/5/12		15ml	0001	Vet

Veterinary Records

Disease controls

Animal ID	Date	Type of infection	Treatment (if applicable) See medicine records	Animal isolated?			Follow up notes
				Yes	No	Date	
Example 0012	02/3/12	TB positive	n/a	X		01/3/12	Removed from herd 08/3/12

Cleaning Records

Date	Area	Chemicals used?	Water Temperature	Cleaning Details			Notes
				Time	Initials	Complete?	
01/01/2019	Bulk Tank	Provide example	Provide record	0830	JB	Y	Visual check undertaken once cleaning completed

Temperature Check Records

Date	Time	Product	Temperature	Method of Recording			Notes
				Manual Probe	Auto Reading	Initials	
01/01/2019	0830	Bulk Tank	3.4C		X	JB	Temperature taken from digital output on tank.
01/01/2019	1115	Final Product Container	2.9C	X		JB	Calibrated probe used to test milk in customer fridge

Annex B: Permitted marketing routes for RCDM