



Production of Raw Drinking Milk for Direct Human Consumption:

A guide to the law in Northern Ireland

Version 3: November 2025

For all queries about this guidance — including if you require the information in an alternative format — please use contact below.

CONTACT <u>nioperationalpolicy@food.gov.uk</u>

Summary

Intended audience:	Food business operators (FBOs) producing raw drinking milk (RDM) of all species
Which UK nations does this cover?	Northern Ireland
Purpose:	This guidance provides advice on both the legal requirements and recommended best practices for the production and sale of raw drinking milk (RDM) from all animal species, where the milk is intended for direct human consumption.
	Please note: this guidance does not cover dairy products made using raw drinking milk, such as cheese, cream, or yogurt.
Legal status:	This guidance has been developed to help producers and distributors of raw drinking milk (RDM) understand and comply with food safety and hygiene legislation.
	It outlines the key legal requirements that apply to the production and distribution of RDM and also includes examples of recommended best practices to support compliance.
	A full list of the relevant legislation can be found in Annex I.
Key words	 Raw Drinking Milk/RDM Dairy products Hygiene and food safety Labelling and composition Pathogens
Review date	November 2025

<u>Contents</u>	<u>Page</u>
Introduction	4
Intended Audience	5
Legal Status of Guidance	6
Definitions	6
Registration Requirements	6
Food Safety Management System (FSMS)/HACCP	7
Tuberculosis (TB) and Brucellosis (BR) Status	9
Antibiotics Residues in Raw Drinking Milk	11
Microbiological Requirements for Raw Drinking Milk	12
Water Supply requirements	15
Recommended Microbiological testing frequency	16
Suggested Testing Schedule	17
Withdrawal and Recall Procedures	19
Reporting Results to DAERA and Verification Testing	19
Labelling of Raw Drinking Milk	20
Minimum durability and Shelf life	22
The sale of Raw Drinking Milk	24
Publication of Compliance Category	25
Review of Guidance	25
Contact Details	26
Annex I: Relevant legislation and guidance	27
Annex II: Glossary	30

Introduction

Background

In recent years, there has been growing interest among milk producers in selling raw, unpasteurised milk directly to consumers. As a result, the volume of raw drinking milk (RDM) being placed on the market has increased significantly.

However, several outbreaks of illness in the UK have been linked to the consumption of RDM. Because of the potential health risks, the Food Standards Agency (FSA) considers RDM a **high-risk food**. Enhanced controls are in place to protect public health. If these measures are found to be insufficient, the FSA may consider introducing further regulatory or legislative actions for the RDM sector.

Purpose of This Guidance

This guidance has been developed by the FSA and DAERA to support food business operators (FBOs) who produce RDM. It aims to help them:

- Understand and manage the risks associated with RDM
- Comply with existing food safety and hygiene legislation

While there have been no recent changes to the law, the FSA is now providing clearer guidance on the controls that should be in place. These controls are intended to help producers demonstrate compliance and ensure their products are as safe as possible.

Important Health Information

Even when good hygiene and safety controls are in place, RDM remains an **inherently high-risk food**. It may contain harmful bacteria that can cause food poisoning.

The FSA advises that **vulnerable individuals** should not consume raw milk, colostrum, cream, or products made from raw milk. This includes:

- Children
- Pregnant women

- Older adults
- People with chronic illnesses
- Individuals with weakened immune systems

Intended audience

This guidance is intended for food business operators (FBOs)—including milk producers and dairy farmers—who are currently supplying or planning to supply raw drinking milk (RDM) from any species for direct human consumption in Northern Ireland.

Its purpose is to help FBOs meet the specific food hygiene requirements that apply to the sale of RDM.

This document complements the existing comprehensive guidance, Milk Hygiene on the Dairy Farm NI, produced jointly by the Department of Agriculture, Environment and Rural Affairs (DAERA) and the Food Standards Agency (FSA). That guidance should be read alongside the advice provided in this document.

Legal status of guidance

This document provides advice, and an informal, non-binding overview of the legal requirements set out in the relevant food safety and hygiene regulations, as listed in Annex I. It is not intended to be a definitive interpretation of the law—only the courts have the authority to make such determinations.

The supply of raw drinking milk (RDM) is governed by both EU and domestic food hygiene legislation. These regulations place full responsibility for the production and supply of safe food—including RDM—on the food business operator (FBO). In the case of RDM supplied directly for human consumption, the FBO is the milk producer or dairy farmer.

This guidance cannot cover every possible situation. You may need to consult the relevant legislation directly to understand how it applies to your specific circumstances. However, following the advice in this document will help you comply with the law.

Definitions

A full glossary of legal definitions and technical terms used in this guidance is provided in Annex II.

Registration Requirements

DAERA (Department of Agriculture, Environment and Rural Affairs)

Under Regulation (EC) No 852/2004, Article 6, all dairy farms producing milk for sale—whether to a milk purchaser and / or directly to the final consumer as raw drinking milk (RDM)—must be registered as a food business for these activities.

In Northern Ireland, this registration process is managed by the Agri-food Inspection Branch (AfIB) of DAERA, on behalf of the Food Standards Agency (FSA).

Contact details for AfIB can be found on page 25 of this document.

AfIB Milk Inspectors carry out official food hygiene controls at dairy farms supplying RDM directly to consumers. These inspections typically take place twice per year or more frequently if problems arise and include checks on RDM bottling, filling operations, and other relevant activities.

District Council

Your local district council is responsible for enforcing regulations related to certain aspects of your raw drinking milk food business, including:

(a) Food Business Registration: It is a legal requirement that all food businesses are registered with their district council.

(b) Food Standards: This includes legislation on the composition of milk (e.g. water and fat content) and labelling requirements.

Before You Begin Supplying RDM

If you are a new RDM producer, you must notify both DAERA AfIB Milk Inspectorate and your District Council at least 28 days before you intend to begin production and sales.

This allows AfIB Milk Inspectors time to provide guidance and to verify that appropriate food safety procedures are in place.

It also allows District Council time to provide guidance on labelling and food standards

⚠ Important:

You must not begin selling RDM until an AflB Milk Inspector has visited your premises and assessed your food safety controls. If you fail to provide advance notice and an inspection later finds inadequate procedures or unsafe product, formal enforcement action may be taken.

Food Safety Management Systems (HACCP)

Under Regulation (EC) No. 178/2002 (General Food Law), the responsibility for producing and supplying safe food—including raw drinking milk (RDM)—rests entirely with the food business operator (FBO). In the case of RDM supplied directly for human consumption, the farmer is the FBO and must ensure that the milk does not pose a health risk to consumers.

One of the most effective ways to manage food safety is by implementing a **documented Food Safety Management System (FSMS)**, often based on the principles of **HACCP** (Hazard Analysis and Critical Control Points).

Why Have a FSMS?

An effective FSMS helps FBOs:

- Demonstrate how they comply with food hygiene regulations
- Identify and control food safety hazards (microbiological, chemical and physical)
- Produce and sell milk that is safe to drink
- Avoid costly food safety incidents, legal action, product recalls, and stock loss
- Protect the reputation of their business

A FSMS typically includes appropriate documentation and record-keeping to support compliance.

The 7 Principles of HACCP

1. Conduct a Hazard Analysis

Identify the hazards in the primary production process —what could go wrong?

2. Determine the Critical Control Points (CCPs)

Identify the most important points in the process where things can go wrong.

3. Set Critical Limits for Each CCP

Limits that let the FBO know when the hazards are not under control.

4. Establish Monitoring Procedures

Carry out regular checks at each CCP to detect problems.

5. Establish Corrective Actions

Decide what to do if something goes wrong, how to fix it, and how to prevent it from happening again.

6. Establish Verification Procedures

Confirm that your HACCP system is working effectively.

7. Establish Documentation and Record-Keeping

Keep clear records to demonstrate your food safety controls and compliance.

Tuberculosis (TB) and Brucellosis (BR) status

In accordance with Regulation (EC) No 853/2004, Annex III, Section IX, raw milk and colostrum must come from animals that are officially free from tuberculosis (TB) and brucellosis (BR)—unless the milk is heat-treated and passes the alkaline phosphatase test. Milk from animals infected with these diseases must never be used for human consumption.

Therefore, **raw drinking milk (RDM)** intended for direct human consumption must come from a herd that is:

- Officially TB Free (OTF)
- · Officially BR Free

Reporting Suspected Disease

If you suspect that an animal may be affected by a **notifiable disease**, including TB or BR, you are legally required to:

- 1. Report it immediately to DAERA Veterinary Service
- 2. **Isolate the animal** until the disease is either confirmed or ruled out More information on notifiable diseases and how to report them is available on the **DAERA website**.

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

Loss of OTF Status

If your herd loses its OTF status—due to a TB breakdown, suspected TB in slaughtered animals, an overdue TB test, or any other reason—DAERA Veterinary Service will notify both:

- You (the FBO)
- The Food Standards Agency (FSA)

In this case:

You will receive a formal notice from DAERA VS stating that all raw milk
 must be heat-treated and must not be sold or consumed in its raw state

- You must immediately cease all RDM sales and notify DAERA AfIB to confirm sales have stopped
- Your registration as an RDM supplier will be suspended

▲ Enforcement action will be taken if RDM sales continue in breach of this notification and relevant food hygiene legislation.

Restrictions on Milk Use

- Milk from non-reactor animals in a herd that has lost its OTF status can only be used if it is heat-treated and passes the alkaline phosphatase test.
- Milk from TB reactor animals must never be used for human consumption, even if heat-treated. It must be withheld from the bulk tank, and DAERA
 Veterinary Service should be contacted for disposal guidance.

Restoring OTF Status

Once your herd has tested negative and regained its OTF status:

- DAERA Veterinary Service will provide written confirmation to you of this status change
- 2. You should then contact your AflB **Milk Inspector** to arrange a visit if you wish to recommence RDM sales.
- 3. The Milk Inspector will
 - Verify that your Food Safety Management System (FSMS) remains effective
 - Review test results to confirm compliance

You **must not resume RDM sales** until you receive **written confirmation** from DAERA AfIB that:

- Your FSMS and milk tests are satisfactory
- Your registration as RDM supplier has been restored.

Further Support

Free advice on how to reduce the risk of TB in your herd is available through **DAERA's** Bovine Tuberculosis Portal.

Antibiotic Residues in Raw Drinking Milk

Food business operators (FBOs) must ensure that **raw drinking milk (RDM)** placed on the market does **not contain antibiotic residues above the legal limits**. These limits are set out in **Regulation (EC) No 37/2010**, which defines the **Maximum Residue Limits (MRLs)** for veterinary medicines in food of animal origin.

Key Responsibilities for FBOs

Maintain accurate medicine records

FBOs must keep detailed records of all veterinary medicines purchased and administered. This includes:

- The identity of the treated animal(s)
- The date and type of treatment
- The withdrawal period

Prevent contaminated milk from entering the food chain

A system must be in place to:

- · Identify animals under treatment
- Ensure their milk is withheld from the bulk tank
- Dispose of it appropriately

Document your procedures

It is best practice to include these procedures in your **Food Safety Management System (FSMS)** or medicine records. This helps demonstrate how you prevent antibiotic-contaminated milk from being sold.

Testing Requirements

If you are only supplying RDM direct to the final consumer and not also through a milk purchaser, you are responsible for testing your milk to demonstrate compliance with MRLs.

Further Guidance

For more detailed advice on preventing antibiotic contamination and testing procedures, refer to:

- Information and guidance on the testing of milk for antibiotic residues
- DAERA's Antibiotic Residues in Milk notes for guidance.

These resources provide practical steps for identifying treated animals, maintaining records, and ensuring compliance with legal requirements.

Microbiological Requirements for Raw Drinking Milk (RDM)

Milk producers must ensure that milk intended for sale complies with the microbiological standards set out in **EU and domestic legislation**.

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:

1. General Microbiological Standards (All Raw Milk)

Raw cow's milk

Somatic Cell Count (SCC):

≤ 400,000 cells/ml (rolling geometric average over 3 months, with at least one sample per month)

Plate Count at 30°C:

≤ 100,000 cfu/ml (rolling geometric average over 2 months, with at least two samples per month)

Raw Milk from Other Species

• SCC: No legal requirement

Plate Count at 30°C:

≤ 1,500,000 cfu/ml (general use)

≤ 500,000 cfu/ml (if used in non-heat-treated products like cheese)

Testing Responsibilities

- Milk Purchasers: Conduct regular testing on behalf of contracted producers
- Direct Sellers: If you sell RDM directly to consumers and do not also have a contract with a Milk Purchaser, you must carry out your own testing to demonstrate compliance.

Non-Compliance and Enforcement

If your milk fails to meet the required standards:

- Notify DAERA AfIB immediately
- Investigate and correct the issue
- If not resolved within 3 months, all raw milk sales must be suspended until compliance is demonstrated

Failure to comply may result in **enforcement action**.

Plate count and SCC are indicators of disease and/or hygiene. To avoid sample fails and to rectify breaches of these standards when identified, the health of the herd should be checked (to control SCC) and hygiene controls assessed (to control Plate count) and where necessary improved. For further help on managing these parameters, please refer to the guidance leaflets for milk producers on DAERA's website.

2. Additional Requirements for RDM Sold Direct to Consumers

Plate Count and Coliforms

Under **Schedule 6 of The Food Hygiene Regulations (NI) 2006**, RDM must also meet the following stricter standards:

• Plate Count at 30°C: ≤ 20,000 cfu/ml

Coliforms: < 100 cfu/ml

These limits are necessary because RDM is not pasteurised and may contain harmful bacteria. Regular testing helps verify that your **Food Safety Management System (FSMS)** is working effectively.

<u>Pathogens</u>

Under Regulation (EC) No 178/2002 and Regulation (EC) No 2073/2005, food must not be placed on the market if it is unsafe. RDM must be free from harmful pathogens.

- Listeria monocytogenes
 - Shelf life ≤ 4 days: Must not exceed 100 cfu/ml (assumed not to grow under refrigeration)
 - Shelf life ≥ 5 days:
 - *Must not be detected in 25ml before leaving FBO control, or
 - Must be proven (via shelf-life studies) not to exceed 100 cfu/ml during shelf life

(*Note: From 1 July 2026, EU Regulation 2024/2895 change this requirement to extend it throughout the proposed shelf life of the product)

- Other Pathogens
- Salmonella spp. Not detected in 25ml
- Campylobacter spp. Not detected in 25ml
- Shiga toxin-producing E. coli (STEC) Not detected in 25ml

Coagulase-positive Staphylococci — < 10,000 cfu/ml
 (Levels between 20 and 10,000 cfu/ml may indicate poor hygiene and require investigation)

Microbiological sampling and testing play a critical role in validating and verifying the effectiveness of control measures applied to raw drinking milk (RDM). These procedures help ensure that the product consistently meets legal safety standards and remains safe for consumption.

Non-Compliance and Enforcement

If your Raw Drinking Milk fails to meet the required microbiological standards, you must:

- Cease sales & notify DAERA AfIB immediately.
- Investigate and rectify the issue.
- Do not recommence sales of RDM until corrective actions have been implemented and follow-up sampling confirms that the process is under control and compliant with legal parameters.

Selling RDM that does not meet the prescribed standards constitutes a legal offence.

Water Supply Requirements

All water used for cleaning food contact surfaces in the milking area, milk storage room (dairy), and milk filling area must be **potable**.

Potable water is defined in **Regulation (EC) No 852/2004**, **Article 2** as water that meets the minimum standards set out in **Council Directive 2020/2184**. In Northern Ireland, this is enforced through the **Water Supply (Water Quality) Regulations (Northern Ireland) 2017**.

To be classified as potable or wholesome and suitable for use in food production premises, **Escherichia coli** and **Enterococci** must be **absent in a 100ml sample** taken from the Food Business Operator's (FBO's) tap used for business purposes.

- Mains Water: If mains water is used, it can generally be assumed to meet
 potable standards. However, it is recommended that the water supply be
 tested annually at the point of delivery to ensure that internal pipework and
 equipment are in good condition and not contributing to contamination.
- Private Water Supplies: Food businesses using a private water supply for
 commercial food and drink production can register with the Drinking Water
 Inspectorate (DWI) via the DAERA Private Water Supplies portal. The DWI
 operates an annual monitoring programme to assess the quality of registered
 supplies.

To demonstrate ongoing compliance, private water supplies should be **routinely tested** for colony counts and pathogens. The **frequency of testing** should be **risk-based** and determined within the business's **Food Safety Management System (FSMS)**.

Recommended Microbiological testing frequency

As part of validating their Food Safety Management System (FSMS), Food Business Operators (FBOs) are advised to submit one full set of satisfactory test results for both water and milk to the AfIB Milk Inspector prior to commencing sales. This initial set should include:

- Plate Count
- Somatic Cell Count (SCC)
- Coliforms
- Pathogens: Salmonella spp., Listeria monocytogenes, Campylobacter spp.,
 Coagulase-positive Staphylococci, and Shiga toxin-producing Escherichia coli (STEC)

FBOs must also implement a sampling and testing regime that provides ongoing assurance of FSMS effectiveness. The frequency of testing should be risk-based, considering the nature of the business, production systems, and existing controls. This should be documented within the FSMS.

Suggested Testing Schedule

Raw Drinking Milk:

Plate Count and Coliforms:

- Weekly for one month
- If results demonstrate compliance, frequency may be reduced to monthly
- If not contracted with a Milk Purchaser, additional plate count tests to confirm compliance with *Regulation* (EC) No 853/2004 as indicated on page 12, point 1 will need to be completed.
- Pathogens (Salmonella spp., Listeria monocytogenes, Campylobacter spp., Coagulase-positive Staphylococci, STEC):
 - Monthly for six months
 - If results demonstrate compliance, frequency may be reduced to sixmonthly

Water Supply:

Mains Supply:

Annual testing at point of delivery

Private Water Supply:

- Monthly testing for three months
- If results demonstrate compliance, frequency may be reduced to sixmonthly
- Tests should include colony count and pathogens

Microbiological Parameter	Satisfactory level (number/100 ml)	Satisfactory level (number/ml)
Escherichia coli (E. coli)	0	N/A
Enterococci	0	N/A
Clostridium	0	N/A

Perfringens		
Coliforms	0	N/A
Colony Count at 22°C	N/A	No abnormal change ¹

¹ Abnormal changes: deviations from the trend identified during routine testing or considerable deviations from results provided by the water supplier or the local authority.

Sampling Guidance: To ensure samples are representative of the final product, testing should be conducted on samples taken from the final container or vending machine.

Laboratory Accreditation: Testing should be carried out by an appropriately accredited laboratory, such as one certified by the **United Kingdom Accreditation**Service (UKAS), to ensure reliability and validity of results.

Corrective Actions Following Unsatisfactory Results in Water

Please adhere to the specific guidelines outlined in the "Water Supply in Food Producing Establishments" guide.

Corrective Actions Following Unsatisfactory Results in Milk

If testing identifies the presence of harmful bacteria (pathogens) or non-compliant plate count/coliform results in milk:

- Sales of raw drinking milk must cease immediately
- DAERA AfIB must be informed
- Increase testing frequency and/or conduct targeted sampling to identify the source of contamination
- Implement corrective actions to prevent recurrence
- Resume supply only after satisfactory results are obtained

Selling raw drinking milk that does not meet legal standards constitutes an offence.

Withdrawal and Recall Procedures

Under **Article 19 of Regulation (EC) No 178/2002**, FBOs must withdraw or recall food from the market if they believe or have reason to believe that it does not comply with food safety requirements. The Enforcement Authority (DAERA/FSA) must also be informed.

- Withdrawal: Removal of unsafe food from the supply chain before it reaches consumers
- Recall: Removal of unsafe food from the supply chain after it has reached consumers, with appropriate consumer notification

FBOs must establish a **documented procedure** for withdrawal and recall, addressing:

- Criteria for triggering the procedure
- Roles and responsibilities for initiating and managing the process
- Methods for notifying customers
- Handling of returned products
- Contact details for relevant staff, customers, and Enforcement Authorities (DAERA/FSA)

Further guidance is available in the <u>UK Guidance on Food Traceability</u>, <u>Withdrawals and Recalls</u>.

Reporting results to DAERA and verification testing

All microbiological test results that do not meet the required standards must be reported to **DAERA** immediately upon receipt. These results will also be reviewed by **AfIB Milk Inspectors** during routine inspections.

Under Schedule 6 of The Food Hygiene (Northern Ireland) Regulations 2006, the Competent Authority has a legal obligation to conduct verification sampling of Raw Cows' Drinking Milk (RCDM). Therefore, in addition to the FBO's own

testing programme, **DAERA AfIB** will carry out independent sampling and testing of RDM to verify compliance with microbiological standards.

- Routine Sampling: DAERA AflB will conduct verification sampling at least twice per year.
- Increased Frequency: Sampling frequency may be increased if there is sufficient evidence to warrant further investigation.
- Statutory Fees: A statutory fee of £63 per sample will be charged by the Food Standards Agency (FSA) to the FBO for cow's milk samples.
 - Note: There is no statutory fee for the sampling and analysis of noncow raw drinking milk.

Labelling of Raw Drinking Milk

Under Schedule 6 of The Food Hygiene Regulations (Northern Ireland) 2006, all raw drinking milk (RDM) must carry a health warning to inform consumers that the milk has not been pasteurised and may contain harmful organisms.

Mandatory Labelling Requirements

All raw milk, regardless of species, must be clearly labelled with:

- Product Name:
 - "Raw milk" (as required by Regulation (EC) No 853/2004)
- Health Warning Statement:
 - "This milk has not been heat-treated and may therefore contain organisms harmful to health. 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."

This statement must be clearly displayed on the container in which the milk is sold.

Use-by Date:

A **use-by date** must be applied, determined through appropriate **shelf-life testing**.

Additional Labelling Scenarios

 Non-prepacked RDM sold in catering settings (e.g. B&Bs or farmhouse kitchens):

The following statement must be:

- (a) Attached to the container, or
- (b) Displayed on a **ticket or notice** clearly visible to the purchaser:

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

Vending Machines:

The health warning must be clearly visible at the point of purchase.

Label Approval and Enforcement

- All labels must be approved by the local Environmental Health Officer (EHO) to ensure compliance with broader food compositional and labelling requirements.
- District Councils (DCs) are responsible for enforcing food labelling regulations, including weights and measures.
- General guidance on labelling for prepacked and non-prepacked foods is available on the Food Standards Agency website

Health Claims and Advertising

While some consumers believe raw milk offers additional health benefits, there are currently no scientifically proven health benefits associated with the consumption of raw milk in Northern Ireland.

Under Regulation (EC) No 1924/2006 on nutrition and health claims, any unsubstantiated health claims may be considered **misleading** and could result in **enforcement action**.

Minimum durability and shelf life

Under Regulation (EU) No 1169/2011, Article 24, foods that are highly perishable from a microbiological perspective must carry a use-by date. After this date, the food is deemed unsafe in accordance with Article 14(2)– (5) of Regulation (EC) No 178/2002.

For **Raw Drinking Milk (RDM)**, which is a ready-to-eat perishable product, the **use-by date** must be established by the **Food Business Operator (FBO)**. This date must reflect the period during which the product remains safe and retains its intended characteristics when stored under recommended conditions.

Exemption for Reusable Glass Bottles

Under Regulation 3 of The Food Information Regulations (Northern Ireland)
2014, reusable glass bottles are exempt from bearing a use-by date. However,
the shelf life of RDM must still be determined, and the Food Standards Agency
(FSA) recommends that durability information be communicated to consumers via:

- · Labelling on individual bottles
- Signage at the point of sale
- Verbal communication

Recommended Consumer Information

In addition to the use-by date and statutory labelling, FBOs should provide:

- Storage conditions: RDM must be kept refrigerated below 5°C
- **Freezing guidance**: If frozen at home on the day of purchase, provide:
 - Storage conditions for frozen milk
 - Instructions for safe defrosting in the refrigerator
 - Shelf life after defrosting, which must not exceed the original use-by date

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

Determining Shelf Life

The method used to determine the use-by date must be documented within the FBO's **Food Safety Management System (FSMS)**. The FBO is responsible for validating and verifying that the FSMS procedures are effective and remain so over time.

Under **Regulation** (**EC**) **No 2073/2005**, FBOs must ensure that food safety criteria—particularly for *Listeria monocytogenes*—are met throughout the product's shelf life under reasonably foreseeable conditions of distribution, storage, and use

To comply, FBOs are required to conduct **shelf-life studies** as outlined in **Annex II of Regulation 2073/2005**. These studies may include:

- Analysis of product characteristics
- Historical data and end-product testing
- Predictive mathematical modelling
- Laboratory-based challenge testing

<u>UK industry guidance</u> is available to help FBOs select appropriate methods for establishing shelf life and demonstrating compliance with *Listeria monocytogenes* criteria.

Expert Support

It is recommended that FBOs seek **expert advice** from accredited microbiological testing laboratories when determining shelf life. The FBO must ensure that the **use-by date is valid** and that the product remains safe until that date.

The Sale of Raw Drinking Milk

Under Schedule 6 of The Food Hygiene Regulations (Northern Ireland) 2006, the sale of raw cows' drinking milk is subject to strict restrictions. These restrictions do not apply to raw drinking milk from non-cow species.

Permitted Sales Channels for Raw Cow's Drinking Milk

Raw cow's milk may only be sold **directly to consumers** through the following approved channels:

- At the farm gate by registered milk production holdings
- In a farmhouse catering operation located on the holding
- At farmers' markets, sold by the FBO or a duly authorised representative
- **Delivered directly to consumers**, provided the sale was initiated on the farm
- Via a distributor operating from a vehicle used as a shop premises (e.g. milk rounds)

Sales through **other outlets**, including retail shops and off-farm farm shops, have been **prohibited since 1985**.

Conditions for Farm Sales

The following practices are accepted by the **Food Standards Agency (FSA)** as compliant with the regulations:

- (a) Farmers' Markets:
 - The FBO or a **duly authorised representative** (e.g. a family member or employee) may sell raw milk at a farmers' market, which is considered an extension of the farm. **Third-party sellers are not permitted.**
- (b) Prearranged Collection:
 - If a **contract of sale** is established on the farm (e.g. customer orders are taken), the FBO or authorised representative may transport the milk to a **prearranged location** for direct exchange with the customer. This is considered **facilitating collection**, not a new sale.

Note: Impromptu sales to passing members of the public at these locations are not permitted.

(c) Direct Delivery:

Following a contract of sale made on the farm, the FBO or authorised representative may **deliver orders directly** to customers, including home delivery.

Prohibited Sales

- Raw cow's milk must not be sold in shops, including:
 - Retail outlets
 - Off-farm farm shops

Only **on-premises farm shops** located at the site of production are permitted to sell raw cow's milk.

Publication of compliance category

The **registration details** of all Raw Drinking Milk (RDM) establishments, along with their **compliance category** following the most recent dairy hygiene inspection, are published on the **Food Standards Agency (FSA)** website:

Raw Drinking Milk Premises in England, Wales and Northern Ireland

Review of Guidance

The FSA is committed to keeping all guidance materials **up to date** and conducts **regular reviews** to ensure continued relevance and accuracy.

Next scheduled review date: November 2027

The FSA welcomes feedback on this guidance, including reports of **broken** links, outdated content, or suggestions for improvement.

Contact Details

For queries regarding the implementation of procedures outlined in this guidance, please contact the **DAERA AfIB team**:

- **Email**: Afib.adminteam@daera-ni.gov.uk
- **Telephone**: 028 9052 0722.

For questions specifically related to this guidance document, please contact the **FSA**Northern Ireland Operational Policy Team:

• **Email**: nioperationalpolicy@food.gov.uk

Annex I: Relevant legislation and guidance

This annex lists the key legislation and guidance documents referenced throughout this guidance. These provide the legal and regulatory framework for the production, sale, and safety of Raw Drinking Milk (RDM) in Northern Ireland.

EU Legislation

• Regulation (EC) No 852/2004

On the hygiene of foodstuffs. Establishes general hygiene rules for all food businesses to protect public health.

Regulation (EC) No 853/2004

Lays down specific hygiene rules for food of animal origin, including milk.

• Regulation (EU) 2017/625

Official Controls Regulation. Establishes rules for the performance of official controls to ensure compliance with food and feed law.

Commission Implementing Regulation (EU) 2019/627

Details the practical arrangements for official controls on products of animal origin.

Regulation (EC) No 2073/2005

On microbiological criteria for foodstuffs. Sets food safety criteria, including for *Listeria monocytogenes*.

• Regulation (EC) No 178/2002

General Food Law Regulation. Establishes the principles of food safety and responsibilities of food business operators.

Regulation (EU) No 1169/2011

On the provision of food information to consumers. Sets rules for food labelling and consumer information.

• Directive (EU) 2020/2184

On the quality of water intended for human consumption.

• Commission Regulation (EU) No 37/2010

On pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

National Legislation (Northern Ireland)

• The Food Hygiene Regulations (Northern Ireland) 2006

Provides for the execution and enforcement of EU food hygiene regulations. Schedule 6 outlines restrictions on the sale of raw milk for direct human consumption.

- The Food Hygiene (Amendment) Regulations (Northern Ireland) 2019 Introduces changes to labelling requirements for Raw Cow's Drinking Milk.
- The Food Information Regulations (Northern Ireland) 2014
 Implements provisions of EU Regulation 1169/2011 on food information to consumers.
- The General Food Regulations (Northern Ireland) 2004 Provides enforcement powers for food safety legislation.

- The Private Water Supplies Regulations (Northern Ireland) 2017
 Sets standards for the quality and monitoring of private water supplies.
- The Water Supply (Water Fittings) Regulations (Northern Ireland) 2009
 Regulates the design, installation, and maintenance of water fittings to prevent contamination.
- The Water Supply (Water Quality) Regulations (Northern Ireland) 2017 Enforces water quality standards in line with EU drinking water directives.

General Guidance

1. FSA – Safer Food, Better Business (SFBB)

& Link

Widely used for small food businesses in England, Wales, and Northern Ireland.

2. FSA - Staff Training Guidance

Offers free training resources on allergens, hygiene, and food safety.

3. WHO - Handwashing Technique Guidance

⊘ Link

WHO's hand hygiene guidelines globally endorsed.

4. FSA - HACCP Guidance

∠ink

Comprehensive guidance on implementing HACCP principles in food businesses.

5. FSA – Guidance Notes for Food Business Operators on Food Incidents

& Link

Provides detailed advice on traceability, withdrawal, and recall procedures.

6. HSE – Control of Substances Hazardous to Health (COSHH) in Catering

Tailored for the catering sector.

7. HSE – Storing Chemical Products (Small Scale)

∠ink

Includes SR24 guidance for small-scale chemical storage.

8. HSE - Diluting Chemical Concentrates

Link to SR2 PDF

Relevant for safe dilution practices.

9. FSA - Guidance on Food Traceability, Withdrawals and Recalls

Comprehensive and up-to-date guidance for UK food businesses.

10. DAERA - Milk Hygiene on the Dairy Farm NI

& Link

Actively referenced by DAERA.

11 Notifiable Diseases in Northern Ireland

DAERA Notifiable Diseases List

Fully up-to-date and includes categorised lists under Regulation (EU) 2016/429.

12.FSA Guidance on Packaging and Labelling

FSA Packaging and Labelling Guidance

Applicable in Northern Ireland under EU Regulation 1169/2011.

13. FSA Guidance on Testing Milk for Antibiotic Residues

Milk Hygiene and Antibiotic Residues

Last updated January 2024

14. Shelf Life of Ready-to-Eat Food in Relation to Listeria monocytogenes

Chilled Food Association Guidance PDF

Endorsed by the FSA and still widely referenced.

15. Technical Guidance on Challenge Tests and Durability Studies for Listeria monocytogenes

EURL Lm Technical Guidance PDF

Version 4 (July 2021) remains the latest and authoritative EU guidance.

16. DAERA Guidance Leaflets for Milk Production

DAERA Milk Production Leaflets

Updated June 2024; includes hygiene, cleaning, and legal compliance resources.

17. Brucellosis Control Surveillance

The general brucellosis control page.

DAERA Brucellosis Control Surveillance

Annex II: Glossary

Coliforms – Bacteria commonly found in the digestive tracts of animals and humans, as well as in soil and plant material. Their presence may indicate contamination.

Contamination – The presence or introduction of a hazard, such as dirt, bacteria, chemicals, or antibiotics, into food or the food environment.

Direct for Human Consumption – Food intended to be consumed by the consumer in the state in which it is obtained, without further processing or treatment.

Food Business Operator (FBO) – As defined in Regulation (EC) No 178/2002, the natural or legal person responsible for ensuring that food law requirements are met within the food business under their control.

Food Safety Criterion – A standard defining the acceptability of a product or batch of foodstuff, applicable to products placed on the market.

Geometric Average – A type of mean calculated by multiplying values together and taking the root corresponding to the number of values (e.g., square root for two values, cube root for three).

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

Inspection – Examination of any aspect of feed, food, animal health, or welfare to verify compliance with legal requirements.

Mains Water Supply – Water provided by the public water supply system.

Maximum Residue Limit (MRL) – The highest concentration of a residue from veterinary medicinal products considered acceptable in or on food. Defined in EU Regulation 470/2009.

Milk First Purchaser – An FBO who buys milk wholesale from producers for processing or treatment within their business.

Monitoring – A planned series of checks (observations or measurements) to assess whether control measures are functioning correctly and to determine the need for corrective actions.

Pathogens – Microorganisms, such as harmful bacteria or viruses, which can cause disease.

Plate Count (Total Viable Count, TVC) – A measure of the concentration of microorganisms in a sample, expressed as colony-forming units (cfu) per gram or millilitre.

Potable Water – Water that meets the standards set out in Council Directive 2020/2184 for human consumption.

Private Water Supply – Any water supply not originating from the public mains.

Raw Drinking Milk (RDM) – Milk from farmed animals that has not been heated above 40°C or undergone equivalent treatment, intended for direct consumption.

Ready-to-Eat – Food intended for consumption without further cooking or processing to eliminate or reduce harmful microorganisms.

Recall – The process of asking consumers to return or dispose of a food product due to safety concerns.

Risk – The likelihood that exposure to a hazard will result in harm or adverse health effects.

Sampling – The collection of food, feed, or environmental substances for analysis to verify compliance with food or animal health laws.

Shelf Life – The period during which a product remains microbiologically safe and suitable under specified storage conditions.

Somatic Cell Count (SCC) – A measure of milk quality, expressed as the number of somatic cells per millilitre of milk.

Validation Checks – Pre-implementation assessments of a Food Safety Management System (FSMS) to ensure it will produce safe food and that identified hazards and controls are appropriate.

Verification – Ongoing checks and reviews to confirm that FSMS procedures are being followed and remain effective.

Withdrawal – The removal of a food product from the market due to safety concerns, before it reaches consumers.

Open Government Licence

© Crown copyright 2019

This publication is licensed under the terms of the Open Government Licence v3.0, except where otherwise stated. Where third-party copyright information has been identified, permission must be obtained from the relevant copyright holders.

To view this licence:

- Visit: https://www.nationalarchives.gov.uk/doc/open-governmentlicence/version/3/
- Email: psi@nationalarchives.gov.uk
- Write to:

Information Policy Team

The National Archives Kew

London

TW9 4DU

FSA Contact and Social Media Links

- Report a Food Safety Concern
 - https://www.food.gov.uk/contact/businesses/report-safety-concern



FSA on X (formerly Twitter): https://x.com/foodgov



Like us on Facebook: facebook.com/foodstandardsagency