

# Raw Milk Ireland

## Industry Guide to Legal Requirements and Good Practice

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#### DOCUMENT REVISIONS

**26<sup>th</sup> October 2018** This guide has been approved for publication by Raw Milk Ireland in conjunction with the Department of Agriculture, Food and The Marine and in consultation with The Food Safety Authority of Ireland.

**20<sup>th</sup> August 2020** Minor updates have been actioned in this guide to refer correctly to new SI of 2020 which references updates in Hygiene Package as well as ERAD policies relating to TB testing in different animal species.

## INTRODUCTION

Producers of Raw milk for direct human consumption who sell more than 30 Litres per week or sell any quantity of raw milk further away from their farm than a 20 km radius must register with the Department of Agriculture, Food and The Marine (DAFM).

### Legislative Background

Following the introduction of Statutory Instrument (S.I) 306 of 2015, the European Union (Food and Feed Hygiene) Regulations 2020 (S.I. 22 of 2020)

- and related EU Regulations (known as the Hygiene Package) – now apply to primary producers supplying in excess of 30 litres of raw milk per week, for direct human consumption, **or** supplying any quantity in excess of a 20km radius from their establishment.

### Registration Process

Such producers of raw milk must register with the DAFM Milk Hygiene Division. In the case of farmers already registered as milk suppliers to other food business operators (FBOs), they should advise their DAFM inspector/contact if they also intend to register with DAFM to supply raw milk directly or via a retailer or food service business to the final consumer.

An information pack including a registration form will be sent to the producer on request.

**Contact:** Milk Hygiene Division,  
Pavilion B, Grattan Business Centre,  
Portlaoise, Co. Laois  
R32 KW50

057 8694355 or [dairyhygiene@agriculture.gov.ie](mailto:dairyhygiene@agriculture.gov.ie)

When the completed registration form is received by DAFM, it is processed/reviewed and a registration number is subsequently allocated e.g. RM01. The registration form, the legislation and other information leaflets applicable to food business operators, and a list of registered producers are also available on the Department's website at

<http://www.agriculture.gov.ie/foodsafetyconsumerissues/foodsafetycontrolsonmilk/> .

## THE PURPOSE AND APPLICATION OF THE GUIDE

This document is an industry guide to legal requirements and good practice. It includes regulatory requirements and provides additional information to the food business operators (FBOs) with a view to reducing the risks associated with raw milk.

Such guides are intended to assist FBOs meet regulatory requirements and to implement robust procedures based on the principles of Hazard Analysis Critical Control Points (HACCP)<sup>1</sup>.

**EU Legislative Background Regarding “Good Practice Guides”**

Regulation (EC) 852/2004 provides inter alia at Articles 7 and 8 that:

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<sup>1</sup> FSAI Booklet on HACCP Guidelines available at [DAFM - Dairy Products](#)

*“Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP principles...”*

*“When national guides to good practice are developed, they shall be developed and disseminated by food business sectors... in consultation with representatives of parties whose interests may be substantially affected, such as competent authorities and consumer groups; ...”*

*“Member States shall assess national guides in order to ensure that... they have been developed in accordance with paragraph 1; their contents are practicable for the sectors to which they refer...”*

It should be noted that **the Scientific Committee of the Food Safety Authority of Ireland (FSAI)** has advised against the consumption of raw milk, based on the potential for contamination by pathogens. Consequently, FSAI reiterates its long-standing view that raw milk poses a risk to consumers and should not be consumed without an appropriate heat treatment. FSAI cautions that even under the best hygiene standards, it is possible that raw milk can pose serious health risks. FSAI strongly recommends that all milk consumed or sold for direct human consumption in Ireland should be pasteurised.

FSAI's views are in keeping with European Food Safety Authority (EFSA) expert opinion that drinking raw milk can pose health risks to consumers and in some cases result in serious illness.

**Raw Milk Ireland (RMI)** is an organisation which is comprised of farmers selling raw milk for human consumption. As an organisation RMI are pleased to have had significant input in to the content of this guideline document and welcomes the introduction of higher standards for producers of raw milk. The farmers involved in RMI are proud of their milk and are dedicated to producing the highest possible quality product.

RMI believe that potential risks with the consumption of raw milk, as with other foodstuffs, must be balanced with the need to respect consumer choice as well as the continued value of food traditions and the consumption of natural unprocessed foods.

Who is this guide designed for?

This guide is applicable to **primary dairy producers**, who supply raw milk for human consumption direct to consumers or to retailers, including food service businesses.

Primary dairy producers, who supply small quantities of raw milk for human consumption below the threshold level of 30 litres per week, where the supply is within 20 km of the producing farm, are currently exempt and outside the scope of the EU Hygiene Package. Such small-scale suppliers may nevertheless subscribe to the guidelines if they wish, on a voluntary basis, in the interest of maintenance of public health standards and in order to facilitate their compliance with food law.

***Notwithstanding the above, small-scale suppliers do still have a legal obligation under article 14 of Regulation 178 of 2002 not to sell unsafe milk for human consumption.***

This guide does not cover producers who use raw milk to make products such as cheese, buttermilk, butter, yoghurt, ice cream etc. who will be required to obtain separate approval from DAFM before they start production. If the situation occurs where an establishment is producing

both raw milk for direct human consumption and for cheese it will not have an extra burden of regulation but will follow whichever may be the stricter set of criteria. The intention is that only one inspectorate responsible for Food Hygiene will be visiting any farm.

(Note: Some requirements in this guide such as pathogen testing are specific to raw milk supply for human consumption, as this poses higher risk than supply for cheese production).

## ANIMAL HEALTH

Raw milk for human consumption must only be sourced from healthy animals.

Only animals with a low somatic cell count (less than 200,000 per ml as per Table 4 below) should be selected for the production of raw milk for human consumption.

Raw milk for human consumption must comply with the animal health requirements of Regulation 853/2004, Annex III, Section IX<sup>2</sup>.

Two health certificates are required annually for milk yielding animals producing raw milk for human consumption and bovine and caprine herds supplying raw milk for human consumption are to be subject to two TB herd tests per year.

Production of raw milk for human consumption is to cease following detection of TB or other infectious zoonotic diseases in the herd. On notification that TB or another infectious disease has been detected in a herd, the food business operator has the responsibility to ensure that any raw milk already produced from animals in the herd must be withdrawn or recalled from sale.

## ANIMAL HUSBANDRY AND MILKING HYGIENE

The animal husbandry system, milking premises and equipment, and milking procedures must be sufficiently hygienic to deliver raw milk direct to the consumer which is safely and hygienically produced.

## PUBLIC HEALTH PLANS AND STANDARD OPERATING PROCEDURES

Suppliers should be adequately trained in food hygiene and food safety prior to commencing trading of raw milk. They must develop and operate documented procedures based on the principles of HACCP with appropriate risk mitigation measures and standard operating practices. Limits and criteria as set out in EU Hygiene regulations will be considered the minimum criteria.<sup>3,4</sup>

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<sup>2</sup> EC Regulation 853/2004 available at [DAFM website](#)

<sup>3</sup> Refer also to The Hazard Analysis Section (Section 5, pages 27-33) of [the cheesemakers workbook on FSAI Website](#).

The HACCP based procedures must be based on the following headings:

- Product and process description and flow diagram
- Hazard identification and hazard analysis
- Control measures and records

The Standard Operating Procedures should cover the following headings:

- Premises Sanitation (Structure and Equipment)
- Personnel hygiene
- Operational hygiene
- Temperature control (chills)
- Water storage, treatment and analysis
- Raw milk requirements
- Microbiological and Chemical testing (including water)
- Prevention of contamination of milk from chemical residues including veterinary drugs and pesticides as well as disinfectants/other cleaning and detergent products
- Equipment Maintenance Programme
- Packaging storage
- Traceability
- Product recall
- Disposal of milk containing antibiotics/other chemical residues
- Pest control
- Personnel training
- Transport of finished product

## STORAGE AND TRANSPORT

The storage and transport arrangements should be included in the Standard Operating Procedures and should comply with EU Regulations regarding temperature controls and general good hygiene practice.

In particular, raw milk must be cooled immediately and maintained at 4 degrees C or lower storage temperature.

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<sup>4</sup> Further refer to the [European Guide for Good Hygiene Practises](https://ec.europa.eu/food/safety/hygiene-practices/good-hygiene-practices/) on ec.europa.eu which includes information and HACCP templates specific to raw milk production.

## Shelf Life

As a preface it must be noted that FSAI strongly recommends that raw milk should have a shelf life of less than or equal to 3 days as a maximum.

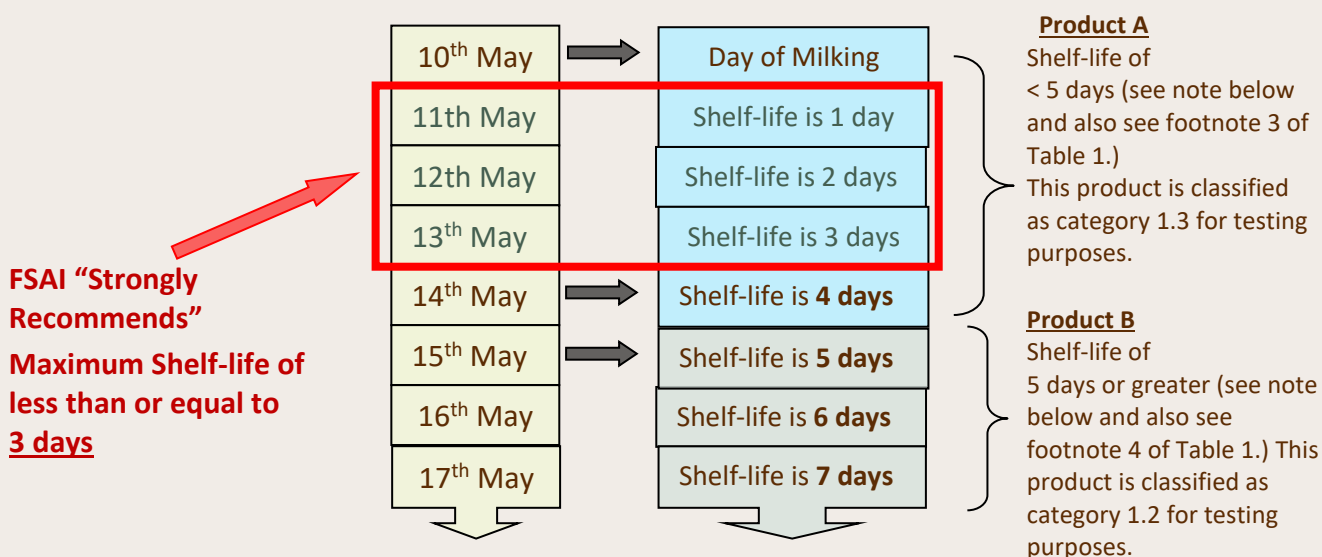
As per Regulation (EC) No 2073/2005, the shelf life of the milk has legal implications for which *Listeria monocytogenes* criterion applies.

These criteria vary dependent on whether the shelf life is less than 5 days or greater than or equal to 5 days. This means that a producer who applies a shelf life of less than 5 days must meet a certain standard, whereas a producer who wishes to apply a longer shelf life of 5 days or greater will be required to meet a more stringent standard (of “not detected in 25ml”), to account for growth, unless the producer conducts a specific type of shelf life study<sup>5</sup>.

The *Listeria monocytogenes* criteria are referred to in Figure 1 and outlined in detail in the “Testing” Section below.

**Note that date of production (milking) is considered to be day 0.**

**Figure 1:** Theoretical example for calculating the “use by date” for raw milk as part of its shelf life and taking A & B product scenarios.



**Product A** is classified as a food that is unable to support the growth of *Listeria monocytogenes*. This is the case with raw milk which has a shelf life of less than 5 days. This product is classified as category 1.3 in Regulation (EC) No 2073/2005.

**Product B** is classified as a food that is able to support the growth of *Listeria monocytogenes*. This product is classified as category 1.2 in Regulation (EC) No 2073/2005.

A product which has a shelf life of 5 days or greater is considered to be in category 1.2.

If the producer conducts a specific type of shelf life study<sup>5</sup> and obtains evidence to demonstrate that 100 cfu/ml will not be exceeded throughout the shelf life, then the limit of 100 cfu/g applies throughout the shelf life.

If the producer does not have this evidence, then the more stringent limit of “not detected in 25ml” applies to raw milk sampled before it has left the immediate control of the food business operator who has produced it. (This type of shelf life testing is separate to the tables listed below and should be carried out by an accredited laboratory).

Producers are also advised to carry out organoleptic tests to ensure the taste of the milk remains at peak throughout the period of the shelf life.

## TESTING

This guide includes the requirement to test for the legal (Regulation 2073/2005<sup>5</sup>) food safety criterion for *Listeria monocytogenes* in a ready-to-eat food. It also includes criteria specific to this guide.

### Microbiological criteria for raw milk sold for consumption without pasteurisation

- **Food Safety Criteria:**

- Products with unsatisfactory food safety criteria results should be recalled and withdrawn from the market.
- The source of the contamination should be investigated and repeated sample(s) should be taken before any more milk is placed on the market.

DAFM must be notified in all cases of breach of food safety criteria.

- **Process Hygiene Criteria:**

- Products with unsatisfactory process hygiene criteria results require a review of hygiene practices and further testing may be required prior to new batches of product being placed on the market.

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<sup>5</sup> For guidance on [Regulation 2073/2005](#) see section of [FSAI website on compliance with the microbiological criteria Regulation](#)



# Food Safety and Process Hygiene Testing of Raw Milk

**Table 1: FOOD SAFETY CRITERIA (Legal Requirement under Commission Regulation (EC) 2073/2005)**

(a) Microorganism/test	Sampling plan		Limits		(b) Reference Method <sup>2</sup>	(c) Stage at which criterion is applicable
	n <sup>1</sup>	c <sup>1</sup>	m <sup>1</sup>	M <sup>1</sup>		
<i>Listeria monocytogenes</i> (Category 1.3 of Regulation 2073/2005 as per footnote 3 below) Product A as per fig.1 above	5	0	100 cfu/ml <sup>3</sup>		EN/ISO 11290-2	Raw milk ready to be placed on the market and during its shelf-life
<i>Listeria monocytogenes</i> (Category 1.2 of Regulation 2073/2005 as per footnote 4 below). Product B as per fig.1 above	5	0	Not detected in 25 ml <sup>4</sup>		EN/ISO 11290-1	Before the raw milk has left the immediate control of the food business operator who has produced it.
	5	0	100 cfu/ml <sup>4</sup>		EN/ISO 11290-2	Raw milk ready to be placed on the market and during its shelf-life

1. n = number of units comprising the sample; c = number of sample units giving values between the limits m and M. **A result is unsatisfactory if M is exceeded in any sampling unit or if the number of sampling units between m and M is greater than c.**

2. Validated alternative methods may be used in accordance with Commission Regulation (EC) 2073/2005 Art. 5.5., for more details see [FSAI guidance on testing foods](#)

3. This limit applies to raw milk with a shelf life of < 5 days.

4. These limits will be applicable to those who are applying a shelf life ≥5 days. If the producer conducts a specific type of shelf life study (see footnote 5 in Shelf Life section of this guide) and obtains evidence to demonstrate that 100 cfu/g will not be exceeded throughout the shelf life, then the limit of 100 cfu/ml applies. If the producer does not have this evidence, then the more stringent limit of “not detected in 25ml” applies.

**Table 2a: FOOD SAFETY CRITERIA (Minimum Sampling recommended by FSAI on the basis of risk as per Regulation (EC) No. 178/2002)**

(a) Microorganism/test	Sampling plan		Limits		(b) Reference Method <sup>2</sup>	(c) Stage at which criterion is applicable
	n <sup>1</sup>	c <sup>1</sup>	m <sup>1</sup>	M <sup>1</sup>		
<i>Verotoxigenic E. coli</i> (VTEC)*	5	0	Not Detected in 25 ml		CEN/ISO TS 13136	Raw milk ready to be placed on the market and during its shelf-life

1. n = number of units comprising the sample; c = number of sample units giving values between the limits m and M. **A result is unsatisfactory if M is exceeded in any sampling unit or if the number of sampling units between m and M is greater than c.**

\* In the absence of an accredited test being commercially available for Milk for VTEC *verotoxigenic E. coli* (also referred to as STEC – *shigatoxigenic E. coli*), testing in Table 2a will be carried out as part of the Official Sampling Plan by the Department of Agriculture, Food & the Marine.

Note that the following highlighted section relates solely to Table 2a above for VTEC testing given that this will be a test undertaken by DAFM and **not** by the raw milk producers until such time as a commercially viable and local testing option may be available to them. If/when this is the case these guidelines will be revised to reflect same with agreement on criteria by all parties.



(Testing criteria relating to other pathogens which will be carried out by the producer can be found in Table 2b below, as well as in other parts of the document more specifically in frequency criteria on page 11).

### DAFM VTEC Surveillance

Sampling will be carried out at a frequency to be determined by DAFM. All VTEC test results will be reported back to the FBO.

Product withholding or recall procedures will not be enacted on the basis of presumptive positives. In the case where VTEC is confirmed in a producer's milk, the supply of raw milk for human consumption must cease immediately.

The DAFM inspectors will follow up, including taking further samples so that undue delay of production does not result.

Based on a reasonable request from a producer for correspondence relevant to their milk which is recalled or withheld, DAFM will make same correspondence available.

### Note from RMI in relation to VTEC/STEC testing:

RMI producers strive to produce the safest milk possible. We recognise the right of DAFM to carry out reasonable testing where appropriate under Regulation (EC) No 852/2004, and we recognise that DAFM have undertaken to bear the cost of testing at this time. However, we note particularly in this section of our industry guidelines (which have been a collaboration between RMI, DAFM and FSAI); some concerns surrounding the implementation of VTEC/STEC testing at the current time (September 2018), where verification methods are not commercial or viably available to the food producers.

We note that at the time of document discussion in August 2018 sampling frequency estimated by DAFM was annually.

We would also note that testing for VTEC is currently only legislated for in one industry (sprouting seeds), and in that instance is only for the major serogroups.<sup>6</sup>

**Table 2b: FOOD SAFETY CRITERIA (Minimum Sampling recommended by FSAI on the basis of risk as per Regulation (EC) No. 178/2002)**

(a) Microorganism/test	Sampling plan		Limits		(b) Reference Method <sup>2</sup>	(c) Stage at which criterion is applicable
	n <sup>1</sup>	c <sup>1</sup>	m <sup>1</sup>	M <sup>1</sup>		
<i>Campylobacter spp.</i>	5	0	Not Detected in 25 ml		ISO 10272-1	Raw milk ready to be placed on the market and during its shelf-life
<i>Salmonella spp.</i>	5	0	Not Detected in 25 ml		EN/ISO 6579	Raw milk ready to be placed on the market and during its shelf-life

1. n = number of units comprising the sample; c = number of sample units giving values between the limits m and M. **A result is unsatisfactory if M is exceeded in any sampling unit or if the number of sampling units between m and M is greater than c.**

2. Validated alternative methods may be used, for more details see [FSAI guidance on testing foods](#)

<sup>6</sup> Commission Regulation (EC) No 2073/2005 as amended by commission Regulation (EU) No 209/2013 of 11 March 2013)

**Table 3: PROCESS HYGIENE CRITERIA (Minimum Sampling recommended by FSAI on the basis of risk as per Regulation (EC) No. 178/2002)**

Microorganism	Sampling plan		Limits		Reference Method <sup>2</sup>	Stage at which criterion is applicable
	n <sup>1</sup>	c <sup>1</sup>	m <sup>1</sup>	M <sup>1</sup>		
Coagulase positive staphylococci ( <i>Staphylococcus aureus</i> and other species)	5	2	10 cfu/ml	100 cfu/ml	EN/ISO 6888-1 or 2	Raw milk at the end of production.  If values >10 <sup>5</sup> cfu/ml are detected, the raw milk has to be tested for staphylococcal enterotoxins.  If enterotoxin is detected the raw milk is considered unsafe.
Enterobacteriaceae	5	1	10 cfu/ml	100 cfu/ml	EN/ISO 21528-1	Raw milk at the end of production.

1. n = number of units comprising the sample; c = number of sample units giving values between the limits m and M. **A result is unsatisfactory if M is exceeded in any sampling unit or if the number of sampling units between m and M is greater than c.**

2. Validated alternative methods may be used, for more details see [FSAI guidance on testing foods](#)

**Table 4: RAW MILK CRITERIA for Plate Count and Somatic Cell Count \***

Microorganism	Sampling plan		Limits *		Reference Method <sup>3</sup>	Stage at which criterion is applicable
	n <sup>2</sup>	c <sup>2</sup>	m <sup>2</sup>	M <sup>2</sup>		
Plate Count @30°C (TBC)	5	2	20,000 cfu/ml	50,000 cfu/ml	EN/ISO 4833	Raw milk at the end of production.
Somatic Cell Count (SCC)	1	N/A	200,000/ml		ISO 21528-2	Raw milk at the end of production.

1. Where approved milk processors are carrying out testing on behalf of the producer and furnishing results it will be possible to use these results for plate count@30 (TBC/ACC) and SCC if the frequency of sampling and the results meet the requirements of these Guidelines.

2. n = number of units comprising the sample; c = number of sample units giving values between the limits m and M. **A result is unsatisfactory if M is exceeded in any sampling unit or if the number of sampling units between m and M is greater than c.** Validated alternative methods may be used, for more details see [FSAI guidance on testing foods](#)

**\*Table 4 - Important Notes:**

Limits are lower than specified in Regulation (EC) No. 853/2004, as suggested by industry to mitigate risk. The limits in Table 4 refer to Cow's Milk

**For raw milk from other species the following applies instead:**

Plate count at 30°C (per ml)	≤ 250,000 (*) <sup>1</sup>
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SCCs are not applicable to raw milk from species other than Bovine.

## Minimum Testing Frequency Requirements for Raw Milk:

### FOOD SAFETY CRITERIA (as referred to in Table 2b above, Table 2a is dealt with separately in its related notes)

- For pathogens (*Listeria monocytogenes*, *Campylobacter* spp, *Salmonella* spp) a minimum of bi-monthly for 6 months should apply.
- If bi-monthly testing (i.e. once every two months) demonstrates compliance, testing can be reduced to quarterly.
- In the case of *Campylobacter* and *Salmonella* following a 12-month testing period demonstrating compliance, composite sampling can be reviewed at inspectorate level where a clear methodology can be put in place for same. In order to demonstrate compliance with the requirements of Regulation (EC) No 2073/2005–any-compositing of samples must be validated by the testing laboratory to demonstrate equivalence with sampling plans set down in the Regulation. Compositing must be validated by the testing laboratory for the matrix for each method in accordance with ISO 6887-1.

### PROCESS HYGIENE CRITERIA/RAW MILK CRITERIA

- Coagulase positive staphylococci, Enterobacteriaceae and *plate count @30°C* (TBC/ACC) fortnightly for one month. If fortnightly testing demonstrates compliance, testing can be reduced to monthly.
- Somatic Cell Count (SCC) - at least one sample per month, unless the competent authority (DAFM) specifies alternative requirement.

## Testing of Water

**Table 5: MINIMUM TESTING REQUIRED ON POTABLE WATER FROM OWN SOURCE**  
*(Taken from Directive 98/83/EC and Commission Directive 2015/1787 Amending Annexes 11 and 111, S.I. 464/2017 The European Union (Drinking Water) Amendment Regulations 2017)*

	Maximum permissible level in Samples (Limits per 100ml)
<i>E. coli</i>	0*
Faecal enterococci	0*
<i>Clostridium perfringens</i> in water that originates from or is influenced by surface water	0*

\*Permissible laboratory test results would generally specify <1 or ND (not detected)

## Minimum Testing Frequency Requirements for Water:

- Mains direct supply - all tests annually.
- Other water supplies - all tests monthly for 3 months. If monthly testing demonstrates compliance with the legislation testing can be reduced to every 6 months.

It is recommended that only laboratories that are accredited<sup>7</sup> (to the ISO standard 17025) for the methods of testing in raw milk are used. Use of an accredited laboratory gives the FBO confidence in the standard and quality of service provided.

When choosing a laboratory, it is recommended to use the FSAI questionnaire<sup>8</sup>. Suppliers should keep a list of laboratories being used by them to carry out their testing. A contract with the laboratory should be put in place to ensure that they understand the requirements of this document and that they are authorised to notify any unsatisfactory results of food safety criteria testing to DAFM.

**Note 1:** If testing confirms the presence of pathogens in the milk (as laid out in food safety criteria Table 1, Table 2a and Table 2b above), **raw milk supply must cease immediately**. Corrective action must be taken to eliminate the presence of pathogens in the raw milk, and the level of testing be increased to verify the corrective action and supply not resumed until satisfactory results are obtained.

If testing identifies out of specification results for the water source, corrective action must be taken to eliminate the contamination. Actions to achieve this will vary depending on the origin of the supply of water and appropriate actions must be discussed with DAFM.

**Note 2:** If testing identifies unsatisfactory levels of indicators organisms (as laid out in process hygiene criteria Table 3 and Table 4 above), hygiene measures must be reviewed.

In the case of unsatisfactory process hygiene criteria results it is advisable and highly desirable for producers to notify their inspectors and work with them to improve procedures.

**Note 3:** Laboratory test results required to monitor and verify the compliance of the raw milk, the hygiene process, and the water potability must be kept on file.

Primary producers supplying raw milk for direct human consumption must report positive/presumptive positive laboratory findings of pathogens in the raw milk and out of specification results in the potable water source to DAFM promptly - i.e. no later than on the same day the producer received notification.

As referred to above - to ensure this outcome is achieved the producer must instruct the private laboratory to notify DAFM immediately where positive or presumptive positives are obtained in the milk and to promptly forward copies of all relevant reports via email to: [dairyhygiene@agriculture.gov.ie](mailto:dairyhygiene@agriculture.gov.ie)

Officials from DAFM will instruct the producer of the required action to be taken on a case by case basis.

It is important to flag that in the case of a reported outbreak a presumptive positive may be considered as the basis for a cessation of supply in certain circumstances. However, generally the

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<sup>7</sup> A list of accredited laboratories and is available from the Irish National Accreditation Board (INAB) [website](#)

<sup>8</sup> See Appendix 1 of [Best Practice for Testing Foods when Assessing Compliance with the Microbiological Criteria Specified in Commission Regulation \(EC\) No 2073/2005](#)

reporting of a presumptive is in order to seek help and only a definitive positive result would require the cessation of supply by the producer.

**Note 4:** Where any testing is carried out by DAFM, full details of the methodology, as well as related correspondence and results in writing will be available to based on a reasonable and relevant request for same by producers as it pertains to their business.

## Trending of results:

Producers should look for trends in their test results by either plotting them or putting them in a table. In the case of the process hygiene criteria in particular, a graph of the results will help the producer see a trend towards unsatisfactory results and allow them to investigate and take appropriate actions to correct the situation.

## Residues Testing:

For raw milk producers who are also supplying milk to an approved milk purchaser, residue testing from the purchaser will be accepted as part of their annual detection plan. Raw milk producers who are not supplying milk to approved milk purchasers will be targeted for sampling by DAFM as part of the National Residue Monitoring Programme.

## **OTHER RECORDS/CHECKS TO BE KEPT ON FILE**

1. Two Animal Health Certificates annually for all dairy herds
2. Two annual TB herd tests for Bovine and Caprine Herds.
3. TB Control Plan for Goats and Sheep.
4. Calibration certificates for the chill.
5. Staff training record
6. Monthly Somatic Cell Count and plate count @30°C records
7. An up-to-date list of all retailers, including food service businesses supplied with raw milk by the producer.
8. Weekly records of quantity of milk sold.
9. Contracts with laboratories carrying out testing.

## LABELLING

The milk must be labelled in compliance with the labelling regulations, and in particular Regulation (EU) No 1169/2011 on the provision of Food Information to Consumers (FIC).<sup>9</sup>

Prepacked raw milk must provide the following information on the label:

1. Name of the food i.e. “Raw Milk” (also in accordance with food hygiene regulations)
2. Name and address of the Business
3. Use by date:

The ‘use by’ date must be indicated as follows:

- (a) it shall be preceded by the words ‘use by ...’;
- (b) the words in point (a) shall be accompanied by:

— either the date itself,

For Example: **“Use By: 3<sup>rd</sup> of March”**

or,

— a reference to where the date is given on the labelling,

To note in the above example, the use by date format would also suffice as meeting the Lot/Batch number requirements where indication of the day and the month appears in the above order, as highlighted.

The particulars for use by date must be followed by a description of the storage conditions, i.e.:

**“Keep Refrigerated”**

4. Any special storage conditions and conditions of use.

In order to ensure that consumers fully understand the risk, a further “health warning” composed by the FSAI and DAFM should also be included legibly on the label of raw milk as follows:

***“This milk has not been heat treated and may contain harmful bacteria. The FSAI strongly advises that , unless it is boiled first, it should not be consumed by children, pregnant women, older people or those who are unwell or have chronic illness”***

5. Net Quantity
6. Identification Mark (In reality this will likely be the registration number of the raw milk producer establishment (i.e. as per the DAFM register, e.g. “RM\*\*.”)

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<sup>9</sup> For more information refer to [FIC requirements on FSAI website](#)

## Information to be provided on non-pre-packed milk

If raw drinking milk is not pre-packed<sup>[2]</sup> and is sold or made available to a consumer at a catering or retail establishment (e.g. at a farm B & B or farm shop/stall/other retailer), the form of words in the health warning (as above) should also appear:

(a) on a label attached to the milk container in which that milk is sold, or offered

(b) on a ticket or notice that is readily discernible by an intending consumer at the place where the consumer chooses that milk.

## Additional relevant information:

Milk is recognised in EU legislation as an allergen and consequently raw milk does not need to have an allergen warning.

Milk is not required to have a list of ingredients.

Raw milk is considered to be an unprocessed product under EU food hygiene regulations and is therefore derogated from the provision of Nutritional information under FIC.

Regulation (EC) 1924/2006 on nutrition and health claims complements the general principles in Regulation (EU) No.1169/2011 and lays down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer.

- Only claims that have been authorised by the European Commission may be stated<sup>10</sup>
- Medical claims that a product can treat human illness or health conditions are not permitted.<sup>10</sup>

## TRACEABILITY AND PRODUCT RECALL/WITHDRAWAL

Traceability is defined by Regulation (EC) 178/2002 as *"the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution"*.

FBOs must have traceability and recall procedures in place which permit identification of and withdrawal/recall of contaminated batches of raw milk which fail to meet the required standards<sup>11</sup>

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<sup>[2]</sup> Pre-packaged foods: 'any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging'

<sup>10</sup> For more information refer to [FSAI Website section on health and nutritional claims](#)

<sup>11</sup> For more information refer to [FSAI guidance on traceability and recall](#)



### **The producer must be able to identify at any point:**

- One step back: The farm from which the milk originated, the date produced and the date supplied.
- One step forward: Details of product supplied i.e.:
  - Customer list\* including contact details. Quantity and batch number(s)<sup>12</sup>
  - Dates of transactions

To be able to meet this requirement, dairy products sold in the European Union must be suitably labelled or identified in order to facilitate traceability – see section on Labeling above.

\*where a producer can reasonably be expected to maintain full customer details e.g. supply to retail or food service or markets and not necessarily individual customers at a market stall

## **Further Notes**

This guide should be reviewed annually by DAFM FSAI and RMI.

Updates in Food law will be taken in to account as well as further input from within the raw milk industry.

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<sup>12</sup> Use by date will also work as a batch/lot number as laid out above within this document.