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SECTION 1

Introduction / Disclaimer

Please take note we have compiled this information solely as the Raw Milk Ireland – a voluntary organisation set up to oppose the now defunct proposed ban of raw milk. And it is not intended to be exhaustive, nor has it been confirmed as accurate by the relevant governing bodies.

SECTION 2

EU Hygiene Regulations Exemption for Direct Sales

The following Text is contained in the below summary and within Regulations 852 and 853 – prior to 2015, this statement / derogation governs the sale of raw milk in Ireland

3. *This Regulation shall not apply in relation to:*

(c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;



Following a new Irish Statutory instrument in 2015 which defines small and local above as 30 litres per week sold within a 20km radius the below entries now form the regulations as the basis for governing the sale of raw milk in Ireland for any farmer selling in excess of the definitions.

SECTION 3

The following sections are excerpts which pertain specifically to raw milk contained within Regulation 853 (laying down specific hygiene rules for food of animal origin)

EU Hygiene Regulation 853 - Information contained within regarding Raw milk

REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 laying down specific hygiene rules for food of animal origin

ARTICLE 1

23) This Regulation should establish criteria for raw milk pending the adoption of new requirements for its placing on the market. These criteria should be trigger values, implying that, in the event of any overshooting, food business operators are to take corrective action and to notify the competent authority. The criteria should not be maximum figures beyond which raw milk cannot be placed on the market. This implies that, in certain circumstances, raw milk not fully meeting the criteria can safely be used for human consumption, if appropriate measures are taken. As regards raw milk and raw cream intended for direct human consumption, it is appropriate to enable each Member State to maintain or establish appropriate health measures to ensure the achievement of the objectives of this Regulation on its territory.

(24) It is appropriate for the criterion for raw milk used to manufacture dairy products to be three times as high as the criterion for raw milk collected from the farm. The criterion for milk used to manufacture processed dairy products is an absolute value, whereas for raw milk collected from the farm it is an average. Compliance with the temperature requirements laid down in this Regulation will not halt all bacterial growth during transport and storage.

Chapter 1 General Provisions

Article 1 Scope

1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.



2. Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation.

3. This Regulation shall not apply in relation to:

- (a) primary production for private domestic use;
- (b) the domestic preparation, handling or storage of food for private domestic consumption;
- (c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;
- (d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat;
- (e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

Article 10 Amendment and adaptation of Annexes II and III

8. A Member State may, of its own initiative and subject to the general provisions of the Treaty, maintain or establish national rules:

- (a) prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption;

Or

- (b) permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses, provided that this does not prejudice the achievement of the objectives of this Regulation.

Article 11 Specific decisions

10. to permit the use for the manufacture of certain dairy products of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards its plate count and somatic cell count; 11. without prejudice to Directive 96/23/EC (1), to fix a maximum permitted value for the combined total of residues of antibiotic substances in raw milk;



ANNEX I DEFINITIONS

4. MILK 4.1. 'Raw milk' means milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40 °C or undergone any treatment that has an equivalent effect.

4.2. 'Milk production holding' means an establishment where one or more farmed animals are kept to produce milk with a view to placing it on the market as food.

SECTION IX: RAW MILK AND DAIRY PRODUCTS

CHAPTER I: RAW MILK — PRIMARY PRODUCTION

Food business operators producing or, as appropriate, collecting raw milk must ensure compliance with the requirements laid down in this Chapter.

I. HEALTH REQUIREMENTS FOR RAW MILK PRODUCTION

1. Raw milk must come from animals:

(a) that do not show any symptoms of infectious diseases communicable to humans through milk;
(b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;

(c) that do not have any udder wound likely to affect the milk;

(d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC;

and

(e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed. 2. (a) In particular, as regards brucellosis, raw milk must come from: (i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC (1), is free or officially free of brucellosis;

(1) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64). Directive as last amended by the 2003 Act of Accession.

(ii) sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC (1);

or

(iii) females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.



(b) As regards tuberculosis, raw milk must come from:

(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis;

or

(ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under a control plan that the competent authority has approved.

(c) If goats are kept together with cows, such goats must be inspected and tested for tuberculosis. 3. However, raw milk from animals that do not meet the requirements of point 2 may be used with the authorisation of the competent authority:

(a) in the case of cows or buffaloes that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the phosphatase test;

(b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, either:

(i) for the manufacture of cheese with a maturation period of at least two months;

or

(ii) after having undergone heat treatment such as to show a negative reaction to the phosphatase test;

and

(c) in the case of females of other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks referred to in point 2(a)(iii) or 2(b)(ii), if treated to ensure its safety.

4. Raw milk from any animal not complying with the requirements of points 1 to 3 — in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC — must not be used for human consumption.

5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 must be effective to avoid any adverse effect on other animals' milk.

II. HYGIENE ON MILK PRODUCTION HOLDINGS



A. Requirements for premises and equipment

1. Milking equipment, and premises where milk is stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk.

(1) Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

2. Premises for the storage of milk must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.

3. Surfaces of equipment that are intended to come into contact with milk (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.

4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of raw milk must be cleaned and disinfected in an appropriate manner before re-use.

B. Hygiene during milking, collection and transport

1. Milking must be carried out hygienically, ensuring in particular:

(a) that, before milking starts, the teats, udder and adjacent parts are clean;

(b) that milk from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk presenting such abnormalities is not used for human consumption;

(c) that milk from animals showing clinical signs of udder disease is not used for human consumption otherwise than in accordance with the instructions of a veterinarian;

(d) the identification of animals undergoing medical treatment likely to transfer residues to the milk, and that milk obtained from such animals before the end of the prescribed withdrawal period is not used for human consumption;

and

(e) that teat dips or sprays are used only if the competent authority has approved them and in a manner that does not produce unacceptable residue levels in the milk.

2. Immediately after milking, milk must be held in a clean place designed and equipped to avoid contamination. It must be cooled immediately to not more than 8 °C in the case of daily collection, or not more than 6 °C if collection is not daily.



3. During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk must not be more than 10 °C. 4. Food business operators need not comply with the temperature requirements laid down in points 2 and 3 if the milk meets the criteria provided for in Part III and either:

(a) the milk is processed within two hours of milking;

or

(b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.

C. Staff hygiene

1. Persons performing milking and/or handling raw milk must wear suitable clean clothes.

2. Persons performing milking must maintain a high degree of personal cleanliness. Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk to wash their hands and arms.

III. CRITERIA FOR RAW MILK

1. The following criteria for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and dairy products.

2. A representative number of samples of raw milk collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4. The checks may be carried out by, or on behalf of:

(a) the food business operator producing the milk;

(b) the food business operator collecting or processing the milk;

(c) a group of food business operators;

or

(d) in the context of a national or regional control scheme.

3. (a) Food business operators must initiate procedures to ensure that raw milk meets the following criteria:

(i) for raw cows' milk: Plate count at 30 °C (per ml) ≤ 100 000 (*)

Somatic cell count (per ml) ≤ 400 000 (**)

(*) Rolling geometric average over a two-month period, with at least two samples per month.



(**) Rolling geometric average over a three-month period, with at least one sample per month, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.

(ii) for raw milk from other species:

Plate count at 30 °C (per ml) $\leq 1\,500\,000$ (*)

(*) Rolling geometric average over a two-month period, with at least two samples per month

(b) However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following criterion:

Plate count at 30 °C (per ml) $\leq 500\,000$ (*)

(*) Rolling geometric average over a two-month period, with at least two samples per month.

4. Without prejudice to Directive 96/23/EC, food business operators must initiate procedures to ensure that raw milk is not placed on the market if either:

(a) it contains antibiotic residues in a quantity that, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90 (1), exceeds the levels authorised under that Regulation;

or

(b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.

(1) Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 546/2004 (OJ L 87, 25.3.2004, p. 13)

5. When raw milk fails to comply with point 3 or 4, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER II: REQUIREMENTS CONCERNING DAIRY PRODUCTS

I. TEMPERATURE REQUIREMENTS

1. Food business operators must ensure that, upon acceptance at a processing establishment, milk is quickly cooled to not more than 6 °C and kept at that temperature until processed.

2. However, food business operators may keep milk at a higher temperature if:

(a) processing begins immediately after milking, or within four hours of acceptance at the processing establishment;



Or

(b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy products.

II. REQUIREMENTS FOR HEAT TREATMENT

1. When raw milk or dairy products undergo heat treatment, food business operators must ensure that this satisfies the requirements of Regulation (EC) No 852/2004, Annex II, Chapter XI.

2. When considering whether to subject raw milk to heat treatment, food business operators must:
(a) have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No 854/2004;

and

(b) comply with any requirements that the competent authority may impose in this regard when approving establishments or carrying out checks in accordance with Regulation (EC) No 854/2004.

III. CRITERIA FOR RAW COWS' MILK

1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before processing:

(a) raw cows' milk used to prepare dairy products has a plate count at 30 °C of less than 300 000 per ml;

and

(b) processed cows' milk used to prepare dairy products has a plate count at 30 °C of less than 100 000 per ml.

2. When milk fails to meet the criteria laid down in point 1, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER III: WRAPPING AND PACKAGING

Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products takes place, by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check.

CHAPTER IV: LABELLING

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1. In addition to the requirements of Directive 2000/13/EC, except in the cases envisaged in Article 13(4) and (5) of that Directive, labelling must clearly show:

(a) in the case of raw milk intended for direct human consumption, the words 'raw milk';

(b) in the case of products made with raw milk, the manufacturing process for which does not include any heat treatment or any physical or chemical treatment, the words 'made with raw milk'.

2. The requirements of point 1 apply to products destined for retail trade. The term 'labelling' includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.

CHAPTER V: IDENTIFICATION MARKING

By way of derogation from the requirements of Annex II, Section I: 1. rather than indicating the approval number of the establishment, the identification mark may include a reference to where on the wrapping or packaging the approval number of the establishment is indicated;

2. in the case of the reusable bottles, the identification mark may indicate only the initials of the consigning country and the approval number of the establishment.

SECTION 4

EU Hygiene Regulations 2005 – Link to Full Documents and Irish Statutory Instrument

European Communities (Food and Feed Hygiene) Regulations 2005 which cover the sale of Raw Milk in Ireland as of Period 2006 to February 2015; specifically:

- Regulation 852: on the hygiene of foodstuffs
- Regulation 853: laying down specific hygiene rules for food of animal origin

The full text of the Relevant EU Food Hygiene Regulations are available here:

[https://www.fsai.ie/uploadedFiles/Reg853_2004\(1\).pdf](https://www.fsai.ie/uploadedFiles/Reg853_2004(1).pdf)

https://www.fsai.ie/uploadedFiles/Reg852_2004%286%29.pdf

The Relevant Irish Statutory Instrument which gave effect to these and other Food and Feed Hygiene EU Regulations is SI 910 of 2005 which came in to effect in 2006:

<http://www.irishstatutebook.ie/2005/en/si/0910.html>