

European legislation for milk



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European common legislation for milk

- Regulation (EC) No 178/2002 laying down general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- Regulation No 852/2004 on the hygiene of foodstuffs
- Regulation No 853/2004 laying down specific hygiene rules for food of animal origin- ANNEX III
- Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products
- Regulation (EU) No 1169/2011 on the provision of food information to consumers
- Commission regulation (EC) No 2073/2005 on microbiological criteria for foodstuff



Regulation (EC) No 178/2002 laying down general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

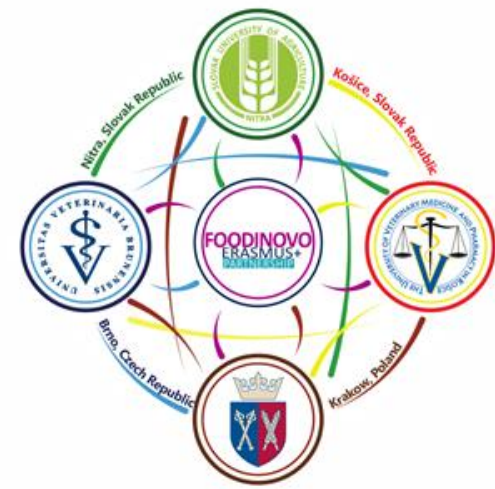


- Food safety requirements:
 - food shall not be placed on market if it is unsafe.
 - food shall be deemed to be unsafe if it is considered to be:
 - injurious to health
 - unfit for human consumption (through decay)



Milk - milk produced by the secretion of the mammary gland of farmed animals

- 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.
- 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.



Regulation No 852/2004 on the hygiene of foodstuffs

- Food business operators' obligations
 - General and specific hygiene requirements
 - Hazard analysis and critical control points
 - Official controls, registration and approval
- Guides to good practice
- Import and exports
- Annex 1 – primary production
- Annex 2 – general hygiene requirements for all food business operators (except when annex 1 applies)



Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

Article 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.



Regulation No 853/2004 laying down specific hygiene rules for food of animal origin



- Food business operators shall place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments:
 - that meet the relevant requirements of Regulation (EC) No 852/2004, those of Annexes II and III of this Regulation and other relevant requirements of food law;
 - and that the competent authority has **registered** or, where required in accordance with paragraph 2, **approved**.

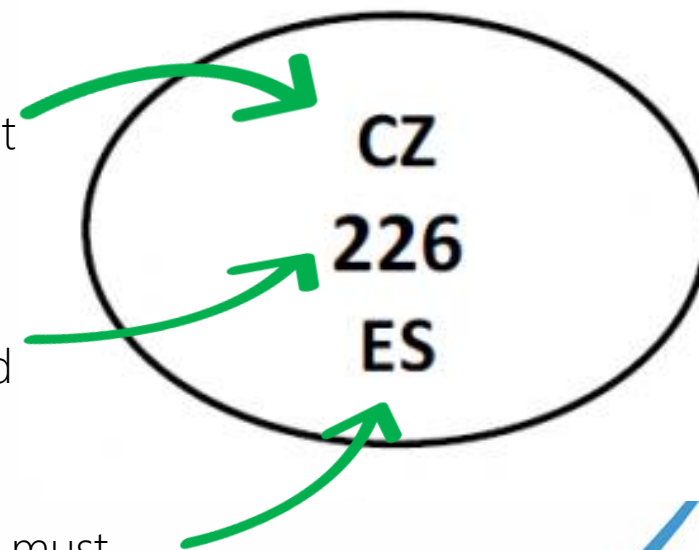


Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

Annex II

The **identification mark** must be applied before the product leaves the production place. The mark must be legible and indelible, and the characters easily decipherable. It must be clearly displayed for the competent authorities.

- The mark must indicate the name of the country in which the establishment located, which may be written out in full or shown as a two-letter code in accordance with the relevant ISO standard.
- The mark must indicate the approval number of the establishment. If an establishment manufactures both food to which this Regulation applies and to which it does not, the food business operator may apply the same identification mark to both types of food.
- When applied in an establishment located within the Community, the mark must be oval in shape and include the abbreviation CE, EC, EF, EG, EK, EO, EY, ES, EÜ, EK, EB, EZ or WE.



Regulation No 853/2004 laying down specific hygiene rules for food of animal origin



Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

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

I. HEALTH REQUIREMENTS FOR RAW MILK AND COLOSTRUM PRODUCTION

1. Raw milk and colostrum must come from animals:

- that do not show any symptoms of infectious diseases communicable to humans through milk and colostrum;
- that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum 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;
- that do not have any udder wound likely to affect the milk and colostrum;
- 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;
- in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.



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Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

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I. HEALTH REQUIREMENTS FOR RAW MILK AND COLOSTRUM PRODUCTION

2. In particular, as regards brucellosis, raw milk and colostrum must come from:

- cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC ([18](#)), is free or officially free of brucellosis;
- sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC ([19](#)); or
- 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.
- As regards tuberculosis, raw milk and colostrum must come from:
 - cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis; or
 - 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.
- If goats are kept together with cows, such goats must be inspected and tested for tuberculosis.



Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

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I. HEALTH REQUIREMENTS FOR RAW MILK AND COLOSTRUM PRODUCTION

3. However, raw milk from animals that does not meet the requirements of point 2 may be used with the authorisation of the competent authority:

- 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 alkaline phosphatase test;
- 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:
- for the manufacture of cheese with a maturation period of at least two months; or
- after having undergone heat treatment such as to show a negative reaction to the alkaline phosphatase test; an
- 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 and colostrum from any animal not complying with the appropriate requirements of points 1 to 3, and 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 and colostrum.



Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

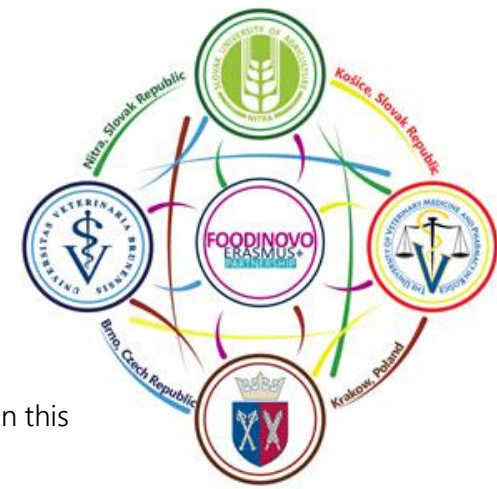
Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

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

II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS

Requirements for premises and equipment

- Milking equipment and premises where milk and colostrum are stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk and colostrum.
- Premises for the storage of milk and colostrum 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.
- Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.
- 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 milk and colostrum must be cleaned and disinfected in an appropriate manner before re-use.



Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

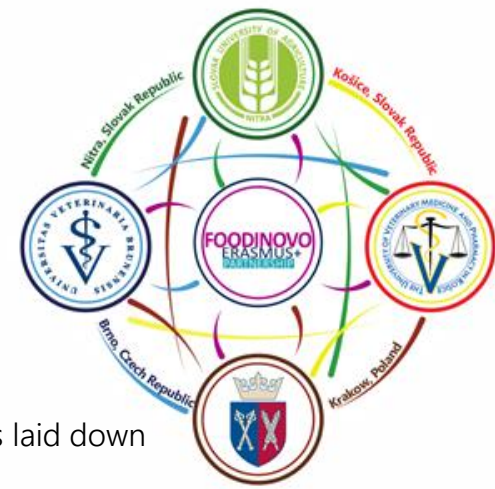
Food business operators producing or, as appropriate, collecting raw milk and colostrum must ensure compliance with the requirements laid down in this Chapter.

II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS

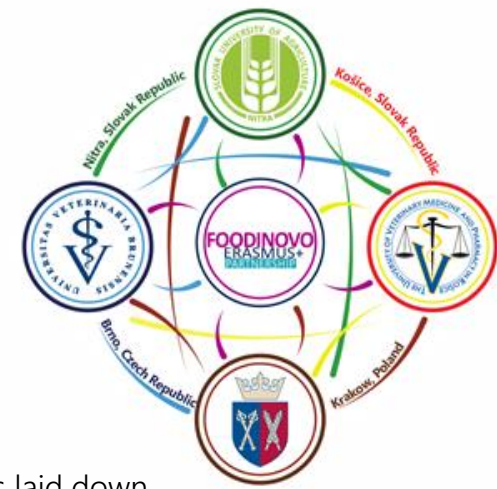
Hygiene during milking, collection and transport

Milking must be carried out hygienically, ensuring in particular:

- that, before milking starts, the teats, udder and adjacent parts are clean;
- that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption
- that milk and colostrum from animals showing clinical signs of udder disease are not used for human consumption otherwise than in accordance with the instructions of a veterinarian;
- the identification of animals undergoing medical treatment likely to transfer residues to the milk and colostrum, and that milk and colostrum obtained from such animals before the end of the prescribed withdrawal period are not used for human consumption; and
- that teat dips or sprays are used only after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ([20](#)):
- that colostrum is milked separately and not mixed together with raw milk.



Regulation No 853/2004 laying down specific hygiene rules for food of animal origin



Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

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

II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS

Staff hygiene

- Persons performing milking and/or handling raw milk and colostrum must wear suitable clean clothes.
- 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 and colostrum to wash their hands and arms.



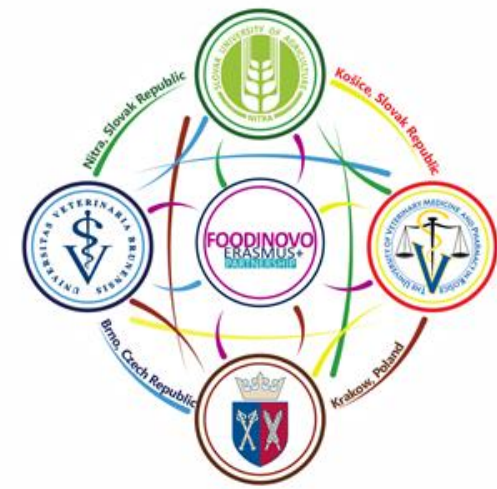
Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

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

III. CRITERIA FOR RAW MILK AND COLOSTRUM –

- see the presentation on mikrobiology of milk and dairy products



Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION REQUIREMENTS CONCERNING DAIRY AND COLOSTRUM-BASED PRODUCTS

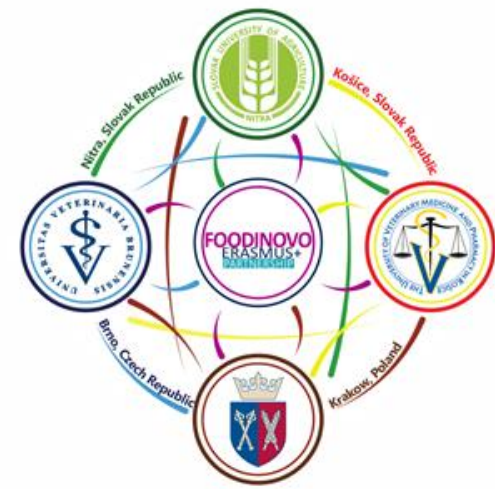
I. TEMPERATURE REQUIREMENTS

Food business operators must ensure that, upon acceptance at a processing establishment,

- milk is quickly cooled to not more than 6 °C;
- colostrum is quickly cooled to not more than 6 °C or maintained frozen,
- and kept at that temperature until processed.

However, food business operators may keep milk and colostrum at a higher temperature if:

- processing begins immediately after milking, or within four hours of acceptance at the processing establishment; or
- the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy or colostrum-based products.



Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

REQUIREMENTS CONCERNING DAIRY AND COLOSTRUM-BASED PRODUCTS

II. REQUIREMENTS FOR HEAT TREATMENT

1. When raw milk, colostrum, dairy or colostrum-based products undergo heat treatment, food business operators must ensure that this satisfies the requirements laid down in Chapter XI of Annex II to Regulation (EC) No 852/2004. In particular, they shall ensure, when using the following processes, that they comply with the specifications mentioned:

- Pasteurisation is achieved by a treatment involving:
 - a high temperature for a short time (at least 72 °C for 15 seconds);
 - a low temperature for a long time (at least 63 °C for 30 minutes); or
 - any other combination of time-temperature conditions to obtain an equivalent effect,
 - such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment.
- Ultra high temperature (UHT) treatment is achieved by a treatment:
 - involving a continuous flow of heat at a high temperature for a short time (not less than 135 °C in combination with a suitable holding time) such that there are no viable microorganisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature, and
 - sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30 °C in closed containers or for seven days at 55 °C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.



Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

Annex III: *RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION*

REQUIREMENTS CONCERNING DAIRY AND COLOSTRUM-BASED PRODUCTS

II. REQUIREMENTS FOR HEAT TREATMENT

2. When considering whether to subject raw milk and colostrum to heat treatment, food business operators must:

- have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No 852/2004; and
- 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.

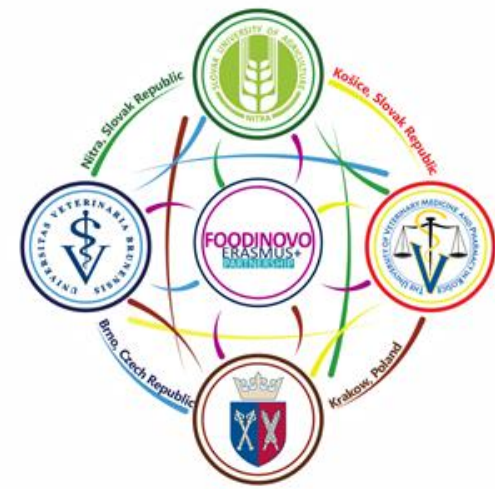


Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

- Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

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 and colostrum-based 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.



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- Annex III: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

LABELLING

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:

- in the case of raw milk intended for direct human consumption, the words 'raw milk';
- 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';
- in case of colostrum, the word 'colostrum';
- in case of products made with colostrum, the words 'made with colostrum'.

The requirements of paragraph 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.



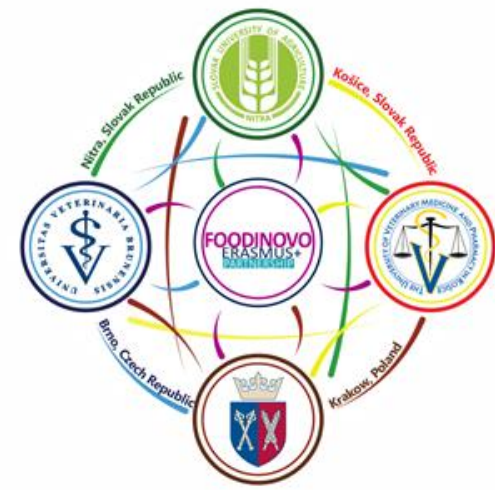
Regulation No 853/2004 laying down specific hygiene rules for food of animal origin

- Annex III: *RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION*

IDENTIFICATION MARKING

By way of derogation from the requirements of Annex II, Section I:

- 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;
- 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.



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



Article 6 - Basic requirement

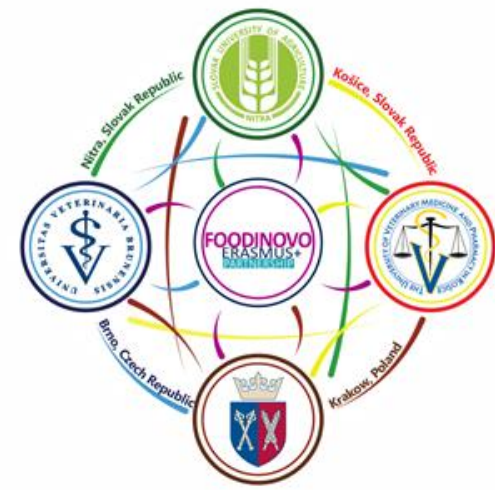
- Any food intended for supply to the final consumer or to mass caterers shall be accompanied by food information in accordance with this Regulation.

Article 7 – Fair information practises

- Food information shall not be misleading



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

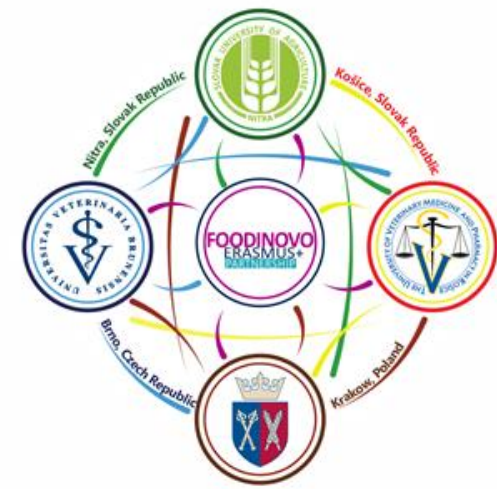


Article 12 and 13: Availability and Placement of mandatory food information; presentation

- Mandatory food information shall be available and shall be easily accessible
- In case of prepacked food – directly on package, durability, country of origin or place of provenance, method of manufacture or production
- Mandatory food information shall be marked in a conspicuous (attractive) place in such a way as to be easily visible, clearly legible (readable) and, where appropriate, indelible (can not be deleted)
- It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.
- The mandatory particulars listed in Article 9(1) shall be printed on the package or on the label attached in such a way as to ensure clear legibility, in characters using a font size where the x-height, as defined in Annex IV, is equal to or greater than 1,2 mm
- In case of packaging or containers the largest surface of which has an area of less than 80 cm² , the x-height of the font size referred to in paragraph 2 shall be equal to or greater than 0,9 mm.



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

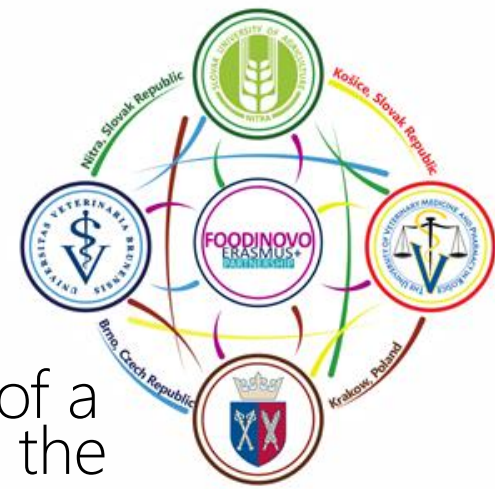


Article 9 - List of mandatory particulars (for milk products is without brackets)

- The name of the food
- (The list of ingredients)
- Allergens
- (The quantity of certain ingredients)
- The net quantity of the food
- The date of minimum durability or the use by date
- Any special storage conditions and/or conditions of use
- The name or business name and address of the food business operator
- (The country of origin)
- Instruction for use where it would be difficult to make appropriate use of the food in absence of such instructions
- A nutrition declaration
- In addition to the particulars listed in Article 9(1),
 - additional mandatory particulars for specific types or categories of foods are laid down in Annex III (for example: packaged in a protective atmosphere, with sweeteners, with sugar and sweeteners)



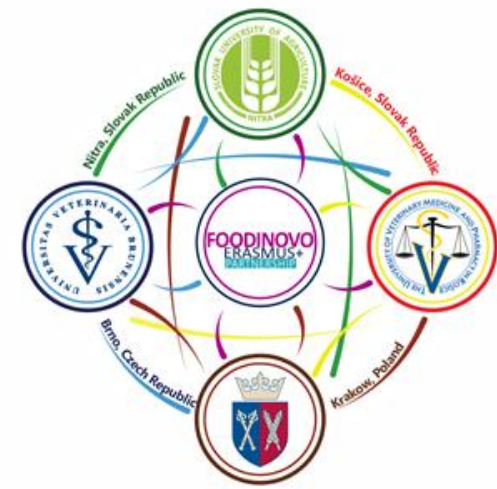
Commission regulation (EC) No 2073/2005 on microbiological criteria for foodstuff



- **food safety criterion** means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market;
- **process hygiene criterion** means a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law;
- When testing against food safety criteria set out in Chapter 1 of Annex I provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002.



Regulation No 1308/2013 establishing a common organisation of the markets in agricultural products

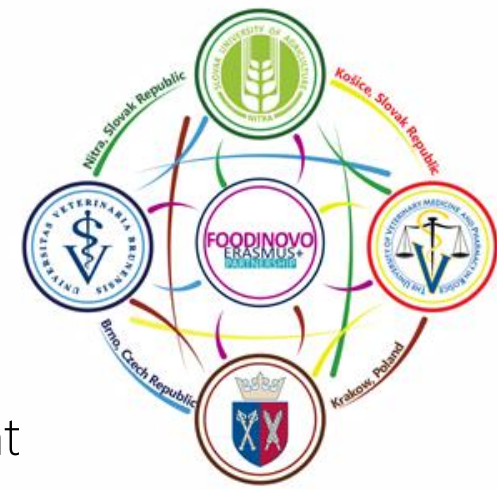


Milk means exclusively the normal mammary secretion obtained from one or more milkings without either addition thereto or extraction therefrom.

- As regards milk, the animal species from which the milk originates shall be stated, if it is not bovine
- The following shall be reserved exclusively for milk products:
 - whey, cream, butter, buttermilk, butteroil, yogurt, kephir, koumiss, viili/fil, smetana, fil; rjaženka, rūgušpiens;



Regulation No 1308/2013 establishing a common organisation of the markets in agricultural products



Drinking milk

- **raw milk:** milk which has not been heated above 40 °C or subjected to treatment having equivalent effect;
- **whole milk:** heat-treated milk which, with respect to fat content, meets one of the following requirements
 - **standardised whole milk:** milk with a fat content of at least 3,50 % (m/m). However, Member States may provide for an additional category of whole milk with a fat content of 4,00 % (m/m) or above;
 - **non-standardised whole milk:** milk with a fat content that has not been altered since the milking stage either by the addition or removal of milk fats or by mixture with milk the natural fat content of which has been altered. However, the fat content may not be less than 3,50 % (m/m);
- **semi-skimmed milk:** heat-treated milk whose fat content has been reduced to at least 1,50 % (m/m) and at most 1,80 % (m/m)
- **skimmed-milk:** heat-treated milk whose fat content has been reduced to not more than 0,50 % (m/m)



Commission decision 2010/791/EU

The products corresponding, on the territory of the Union, to the products referred to in the second subparagraph of point III(1) of Annex XII to Regulation (EC) No 1234/2007 are listed in Annex I to this Decision.

Coconut milk

'Cream ...' or 'Milk ...' used in the description of a spirituous beverage not containing milk or other milk products or milk or milk product imitations (for example, cream sherry, milk sherry)



Partly or wholly dehydrated milk

Council directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption

Article 1: This Directive shall apply to partly or wholly dehydrated preserved milk defined in Annex I.



Partly or wholly dehydrated milk: Council directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption

Article 3: The product names listed in Annex I (Partly dehydrated milk and totally dehydrated milk) shall apply only to the products referred to therein and shall, without prejudice to subparagraph (b), be used in trade to designate them;



ANNEX I

DEFINITIONS OF PRODUCTS AND PRODUCT NAMES

1. Partly dehydrated milk

▼ M1 ▼

This means the liquid product, whether or not sweetened, obtained by the partial removal of water from milk, from wholly or partly skimmed milk or from a mixture of these products, which may have an admixture of cream or of wholly dehydrated milk or both, the addition of wholly dehydrated milk not to exceed, in the finished products, 25 % of total milk solids.

▼ B ▼

— Types of unsweetened condensed milk

—

(a) Condensed high-fat milk

Partly dehydrated milk containing, by weight, not less than 15 % fat, and not less than 26,5 % total milk solids.

(b) Condensed milk

Partly dehydrated milk containing, by weight, not less than 7,5 % fat and not less than 25 % total milk solids.

(c) Condensed, partly skimmed milk

Partly dehydrated milk containing, by weight, not less than 1 % and less than 7,5 % fat, and not less than 20 % total milk solids.

(d) Condensed skimmed milk

Partly dehydrated milk containing, by weight, not more than 1 % fat and not less than 20 % total milk solids.



Partly or wholly dehydrated milk: Council directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption

Article 3: as an alternative to the product names referred to in subparagraph (a), Annex II provides a list of particular designations. These designations may be used in the language and under the conditions laid down in Annex II.



ANNEX II

PARTICULAR DESIGNATIONS FOR CERTAIN PRODUCTS LISTED IN ANNEX I

- (a) The English term 'evaporated milk' means the product defined in Annex I(1)(b) containing, by weight, at least 9 % fat and 31 % total milk solids.
- (b) The French terms 'lait demi-écrémé concentré' and 'lait demi-écrémé concentré non sucré', the Spanish term 'leche evaporada semidesnatada', the Dutch terms 'geëvaporeerde halfvolle melk' or 'halfvolle koffiemelk' and the English term 'evaporated semi-skimmed milk' mean the product defined in Annex I(1)(c) containing, by weight, between 4 % and 4,5 % fat and not less than 24 % total solids.
- (c) The Danish term 'kondenseret kaffefløde' and the German term 'kondensierte Kaffeesahne' mean the product defined in Annex I(1)(a).
- (d) The Danish term 'flødepulver', the German terms 'Rahmpulver' and 'Sahnepulver', the French term 'crème en poudre', the Dutch term 'roompoeder', the Swedish term 'gräddpulver' and the Finnish term 'kermajauhe' mean the product defined in Annex I(2)(a).
- (e) The French term 'lait demi-écrémé concentré sucré', the Spanish term 'leche condensada semidesnatada' and the Dutch term 'gecondenseerde halfvolle melk met suiker' mean the product defined in Annex I(1)(f) containing, by weight, between 4 % and 4,5 % fat and not less than 28 % total milk solids.
- (f) The French term 'lait demi-écrémé en poudre', the Dutch term 'halfvolle melkpoeder' and the English terms 'semi-skimmed milk powder' or 'dried semi-skimmed milk' mean the product defined in Annex I(2)(c) with a fat content of between 14 % and 16 %.
- (g) The Portuguese term 'leite em pó meio gordo' means the product defined in Annex I(2)(c) with a fat content of between 13 % and 26 %.
- (h) The Dutch term 'koffiemelk' means the product defined in Annex I(1)(b).
- (i) The Finnish term 'rasvaton maitojauhe' means the product defined in Annex I(2)(d).



Partly or wholly dehydrated milk: Council directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption



- The labelling must state the percentage of milk fat, expressed by weight in relation to the finished product, except in the case of the products defined in Annex I(1)(d) and (g) and Annex I(2)(d), and the percentage of fat-free dried milk extract in the case of the products defined in Annex I(1). These particulars shall appear near the trade name.
- In the case of the products defined in Annex I(2), the label must state the recommendations as to the method of dilution or reconstitution, including details of the fat content of the product thus diluted or reconstituted.



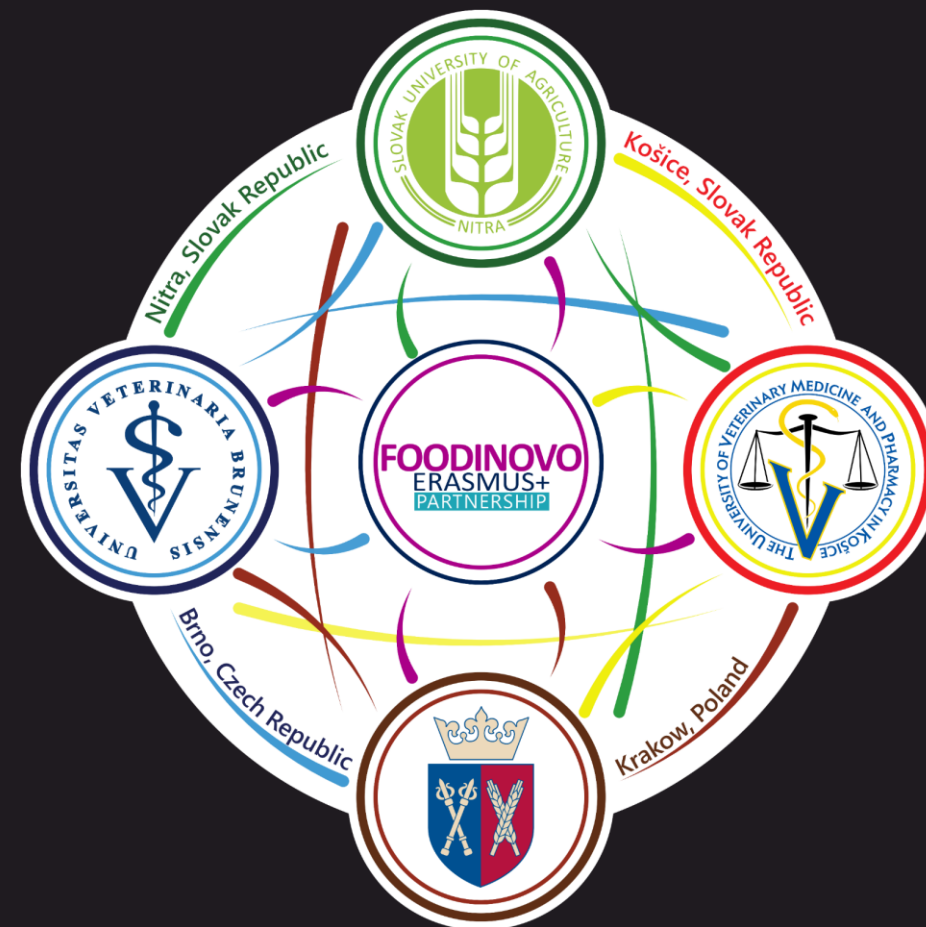
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Innovation of the structure and content of study
programs profiling food study fields with a view to
digitizing teaching

Táto publikácia bola spolufinancovaná programom
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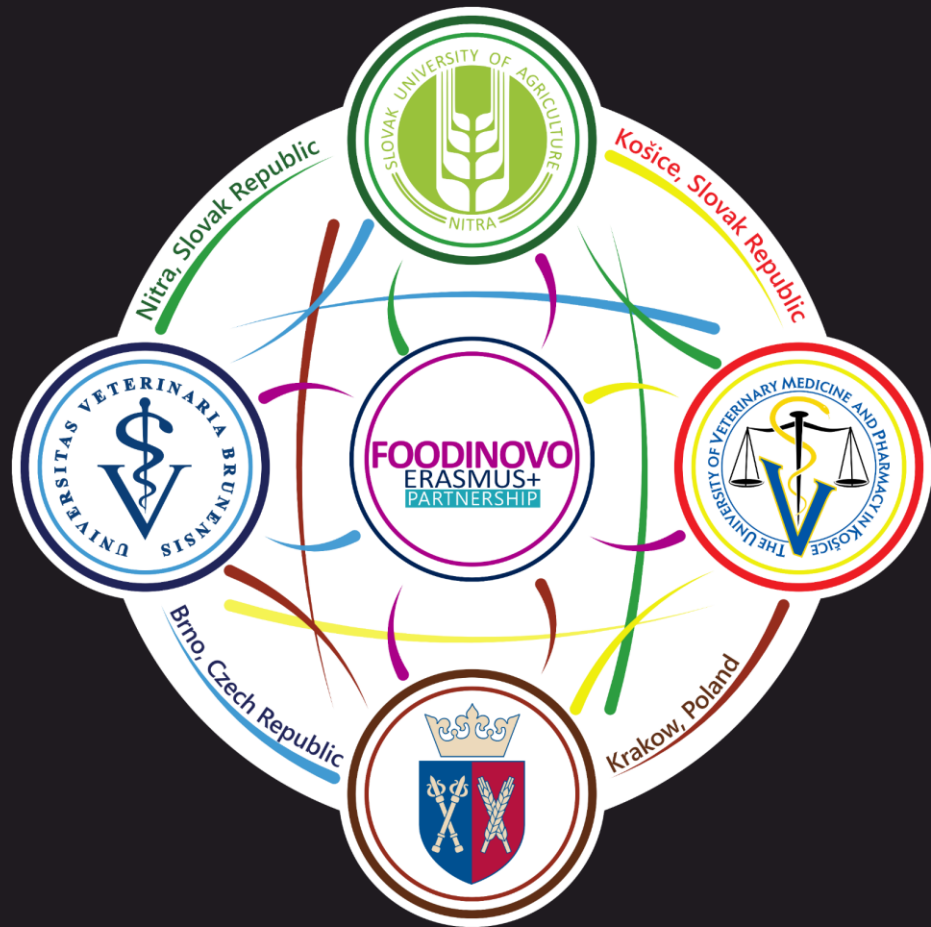
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študijné odbory s ohľadom na digitalizáciu výučby

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