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Overview of the milk and dairy products legislation in the European Union

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Abstract

European Union legislation laying down rules for the dairy sector. The legislation defines the conditions under which milk and milk products intended for human consumption can be imported into the EU. Milk and milk products must come only from third countries that appear on the list of authorized countries. Establishments, where milk and milk products are produced, must be approved for export. The TRACES system is used on imports and the consignment must be accompanied by a certificate. This system ensures product traceability and prevents the introduction of diseases. An important role is delegated to the designated border control posts (BCPs) where the appropriate customs and veterinary inspections are performed by government institutions of the country. The European Union has adopted legislation to ensure the safety of food placed on the market in EU member countries. This legislation sets general hygienic requirements for food production based on the good manufacturing practice and the HACCP system. The criteria for microorganisms, chemicals, and applicable food additives are set. Also, the legislation contains requirements for product labeling. Part of the legislation concerns the common organization of the market in milk and milk products. These regulations contain rules for direct payments, subsidies, define the school milk system, etc. Specific legislation creates rules for organic bio food production, for production and labeling of products with the Protected Geographical Indication, Protected Designation of Origin, and Traditional Specialty Guaranteed. There is also legislation that defines the labeling of products intended for specific populations, e.g. gluten-free foods, lactose-free foods, etc. Areas not regulated by the legislation include the labeling of products with certification marks designed to highlight the suitability of food for religious purposes or quality certification.

Keywords: milk, dairy products, legislation

1. Introduction

European Union legislation contains several pieces of legislation that comprehensively address the entire dairy sector. The legislation defines the conditions under which milk and milk products intended for human consumption can be imported into the EU. Milk and milk products must come only from third countries that appear on the list of authorized countries. Establishments, where milk and milk products are produced, must be approved for export. TRACES is used on import and the consignment must be accompanied by a certificate. This system ensures product traceability and prevents the introduction of diseases [24]. The European Union has adopted several pieces of legislation that establish rules for the production and marketing of safe food in individual EU countries. This legislation sets hygienic limits for the content of foreign substances, and microorganisms define requirements for traceability and labeling of products. Part of the legislation concerns the common organization of the market in milk and milk products. These regulations set out the rules for direct payments, and subsidies. Specific legislation creates rules for organic food production. The European Union also has specific legislation that defines the rules for labeling products with the Protected Geographical Indication, Protected

Designation of Origin, and Traditional Specialty Guaranteed. There is also legislation in the EU that define the labeling of products intended for at-risk populations, e.g. gluten-free foods, lactose-free foods, etc. Areas not regulated by the legislation include the labeling of products with certification marks designed to highlight the suitability of a food for religious purposes or quality marks [25]. In this article, we have summarized the legislation that applies in the European Union for milk and dairy products. In the text and the tables, in most cases, we list the legislation without amendments, which can be found directly in the Eurlex databases we have worked with. In this article, we have summarized the legislation that applies in the European Union, hygiene manuals, ISO standards and *Codex Alimentarius* standards for milk and dairy products.

2. General health rules

Regulation (EU) No 182/2011 of the European Parliament and of the Council [2016/429](#) [1] of 9 March 2016 on communicable animal diseases and amending and repealing certain acts in the field of animal health and Commission Delegated Regulation (EU) [2020/692](#) [2] supplementing Regulation (EU) of the European Parliament and the Council [2016/429](#) [1] lay down rules concerning the entry into, and the movement and treatment of, consignments of certain products of animal origin after they enter into the Union. The conditions for entry into the Union of raw milk, milk products, colostrum, and colostrum-based products shall be based on the animal health risks posed by those products. These risks are linked to the country or territory of origin or their zone and to the species of animals from which these products were obtained. In the case of milk and colostrum, two diseases are a cause for concern - foot-and-mouth disease and bovine fever virus infection, and therefore raw milk and colostrum should only enter from third countries or territories or zones free of these diseases. Consumer health protection is ensured by the application of several pieces of EU legislation: Regulation (EC) No [178/2002](#) [3], Regulation (EC) No [852/2004](#) [4], Regulation (EC) No [853/2004](#) [5], Regulation (EC) No [2017/625](#) [6], [2019/627](#) [7] form the legal basis for the production, trade and official control of food of animal origin. The general food regulation principles are well described by [42].

3. Imports of milk and dairy products for human consumption into the EU

Harmonized EU legislation makes it possible to apply the same requirements for the marketing of milk and milk products in all Member States and prevents milk and milk products that can transmit infectious diseases dangerous to livestock or humans from entering the EU.

These principles also apply to consignments that are under EU transit and/or temporary storage procedures. Depending on the risk they may pose, such consignments are exempted from public health requirements but must comply with veterinary requirements.

In general, the products must come from countries that are allowed to enter milk and dairy products into the EU.

The establishment of origin must be approved and authorized as an establishment from which milk and milk products may be imported into the EU.

The third country of origin must have an approved residue control plan.

A non-EU country must meet certain requirements to obtain a marketing authorization for milk and dairy products. The most important aspects to consider before authorization are:

- the organization, structure, competencies, and powers of the veterinary services,
- third-country legislation,
- non-EU country rules on animal disease prevention and control,
- the health status of livestock, other domestic animals and wildlife,
- the regularity and speed of information on infectious animal diseases provided by the third country to the European Commission and the World Organization for Animal Health (OIE),
- hygiene requirements for the production, handling, storage, and dispatch of products of animal origin.

4. Audit

Before a non-EU country obtains authorization to place milk and dairy products on the EU market, the European Commission can carry out an audit to verify that all the criteria set out in EU legislation are properly met.

5. Authorized third countries and establishments

Based on the principles contained in EU legislation and the results of the Commission's audit, a non-EU country may be included in the list of third countries eligible for the entry of milk and milk products into the EU.

The list of these third countries provides Commission Implementing Regulation (EU) [2021/405](#) [8] of 24 March 2021 establishing the lists of third countries or regions thereof from which, by Regulation (EU) No

2017/625 [6] authorizes the entry into the Union of certain animals and goods intended for human consumption. Before exporting milk and dairy products to the EU, the country must be listed.

All imports of milk and milk products into the EU must come from an approved establishment that has been authorized and listed for this purpose. Third countries are responsible for updating the lists of installations and informing the Commission of any changes. Lists of establishments in non-EU countries authorized to produce fresh meat are published on the Commission's website.

6. Certificate

Consignments of milk and milk products entering the EU must be accompanied by a CHED certificate. The model certificate is set out in the Commission Implementing Regulation (EU) **2020/2235 [9]** (Chapter, 33, 34, 25 - sample certificates).

7. Public health

Public health requirements must be met. For example, a non-EU country is required to have an approved monitoring plan for "residues". Products placed on the market in the EU must comply with the requirements of food law, namely Regulation (EC) No **178/2002 [3]**.

8. Border control

Regulation of the European Parliament and the Council (EU) **2017/625 [6]** lays down the principles governing the organization of veterinary checks on products of animal origin entering the EU from outside the EU at border inspection posts.

Milk and milk products entering the EU are checked at the EU Border Control Station (BIP) by the Commission Implementing Regulation (EU) **2019/1014 [10]** laying down detailed rules concerning minimum requirements for border inspection posts, including inspection centers. Member States' official veterinarians ensure that milk and milk products comply with all requirements laid down in EU legislation.

9. TRACES NT system

TRACES NT (Trade Control Expert System - New Technology) is the European Commission's online system for sanitary and phytosanitary certification required for the import of animals, animal products, food, and feed of non-animal origin and plants into the European Union, and for intra-EU trade, and animal exports and certain animal products from the EU. Exporters from third countries who plan to export products of animal origin to the EU must be registered in this system through the European Commission, which must be contacted for this purpose by the competent authority of the third country.

Detailed rules for operations to be carried out during documentary, identification, and physical checks on animals and goods subject to official controls at border inspection posts and following those controls are defined in the Commission Implementing Regulation (EU) **2019/2130 [11]**.

From 14 December 2019 (date of application of the Regulation on official controls - Regulation (EU) **2017/625 [6]**), the use of the Common Health Entry Documents (CHED) has become mandatory for the entry of animals and goods into the EU under Article 47 of this Regulation. The CHED document has several variants (A, P, PP, D), while the CHED-P document is required for the import of dairy products. CHED-P is a common medical entry document for consignments of products of animal origin, germinal products, and animal by-products (EC, 2022).

It is issued by the veterinary authorities in TRACES after an inspection. The first part must be completed by the importer to notify in advance of the import or transit of animal products in the EU 24 hours before the arrival of the goods. The second part of the form is filled in by the relevant veterinary and food administration, which confirms that it has carried out checks at the border inspection post and authorizes the entry of the products into the EU.

10. Traceability

The food traceability requirement is defined by Regulation (EC) No **178/2002 [3]** as amended. This Regulation contains general principles for the traceability of food.

Traceability in the Dairy Industry in Europe is well described in [28] by [29] and the perceived value of dairy product traceability in modern society was analyzed by [41]. Traceability means the ability to find and trace food, feed, food-producing animals, or substances that are intended or intended to be added to food or feed at all stages of production, processing, and distribution. Traceability of dairy products is important to solve the problems with hazards identified in the dairy products noted in RASFF system [30].

Stages of production, processing, and distribution mean any stage, including import, from, and including primary food production to and including storage, transport, sale, or delivery to the final consumer and, where relevant, import, production, storage, transport, distribution, sale, and feed delivery.

Food and feed business operators (FBOs) must:

1. Ensuring the traceability of food, feed, food-producing animals, and any substances which are intended to be added to or intended to be added to food or feed must be established at all stages of production, processing, and distribution.
2. Be able to identify any person who supplies them with food, feed, a food-producing animal, or any substance intended to be added to food or feed or which is intended to be added to food or feed. To this end, such operators must have systems and procedures in place that allow this information to be made available to the competent authorities upon request.
3. Have systems and procedures in place to identify other businesses to which their products are supplied. This information shall be made available to the competent authorities upon request.
4. Foods or feedingstuffs which are placed on the market or are likely to be placed on the market in the Community must bear an appropriate label or marking enabling them to be traced through appropriate documentation or information by the relevant requirements of the more specific provisions.

11. Food labeling

Milk and dairy products must be labeled by:

- Regulation (EU) No **931/2011** [13] on the traceability of animal products,
- EC Regulation No **1169/2011** [14] on the provision of information to consumers,
- EC Regulation No **1308/2013** [15] on the common organization of the markets in agricultural products.
- The products must bear an oval veterinary mark.
- Nutrition and health claims may be made on products by Regulation (EC) No 258/97 of the European Parliament and the Council **1924/2006** [16]. Functional Foods and Health Claims Legislation is important and only the claims allowed by legislation should be used by food business operators [33].
- The product can contain several symbols present in Table 1 [17].

Standards and labeling of milk fat and spread products in different countries in the world are different [32]. The impact of new EU Regulation No. 1169/2011 was analyzed by several authors [36], [37], [38], [39] and [40].

The traceability requirements for food of animal origin are set out in Implementing Regulation (EU) No **1095/2010** [12], **931/2011** [13].

To ensure traceability, the following are required:

- the name and address of the FBO supplying the food, and
- the name and address of the FBO to which the food was delivered.

Regulation (EU) No **931/2011** [13] applies to all FBOs at all stages of the production, processing, and distribution of food of animal origin, including primary producers, retailers, wholesalers, intermediaries, storers, and transporters of food of animal origin.

All products of animal origin placed on the market have been marked with a health mark or identification mark.

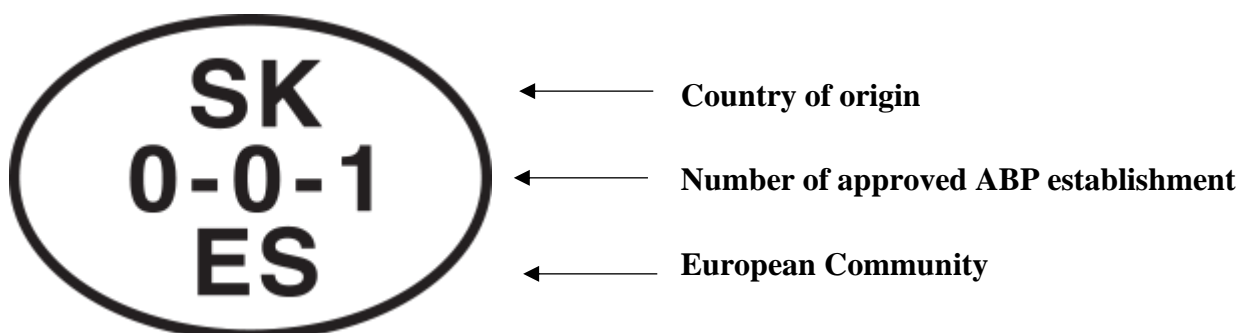








Figure 1 Example of the European union health and identification mark. Note: SK – Slovakia, ES – European Community.

Table 1 Food Packaging Symbols Explained.

Symbols	Definition
	This symbol is often used on containers, such as Tupperware, to show that the product is suitable for food use. It may or may not have the word “food” below the cup and fork.
	Recycling – this logo is used internationally to show that the product can be recycled. This is not an indication that the packaging has been made from recycled material.
	If you see a number in the middle of this image, that is to indicate the percentage of recycled material that makes up that product. The Green Dot In Continental Europe the ‘Green Dot’ trademark indicates that a fee has been paid to fund the recycling of the product. It is a financial symbol principally and indicates that the producer is part of PRO Europe’s packaging recovery organisation, a company that seeks to promote economic producer responsibility. In the UK it is often used incorrectly on products to suggest they are recyclable. This is a misuse of the symbol.
	Plastic recycling – another widely used symbol to show that the plastic used in the packaging can be recycled. The PET refers to Polythene Terephthalate which is commonly used in this application. The number inside (1 – 7) defines the resin used in making the packaging.
	Keep Britain Tidy – this symbol is included to remind consumers to dispose of their waste in an appropriate manner. It does not necessarily relate to the type of packaging used, but is rather a campaign against littering.
	The Forest Stewardship Council The FSC looks after our forests and can be found on all wood and paper products as well as products such as latex that are derived from trees. The FSC logo can be found on products such as decking, charcoal, and kitchen utensils. When you buy a product with the FSC label, it’s a guarantee that the trees used were replaced or allowed to grow naturally, that the rights of indigenous people are protected, and that the homes of wildlife are conserved.

12. Production

The production of dairy products is subject to the general hygiene requirements set out in several European regulations(EC): Regulation (EC) No **178/2002** [3], Regulation (EC) No **852/2004** [4], Regulation (EC) No **853/2004** [5], [34]. The processed milk must meet the hygienic requirements, which are the total number of microorganisms, the number of somatic cells, the absence of residues of veterinary drugs, and not exceeding the maximum permissible amounts of certain contaminants. The purchase of milk takes place in the form of a contractual relationship with the primary milk producer. In production, input, inter-operational, and output control is performed by the HACCP plan. The controls are also focused on the pasteurization regime, reaching the prescribed temperature and time of pasteurization as well as on the inactivation of the enzyme alkaline phosphatase. From a microbiological point of view, the legislation sets limits specifically for the production process and final products. The products must not be contaminated with pathogenic microorganisms, foreign contaminants, and physical objects. The quality requirements for raw milk as well as the final product are determined by each producer, taking into account existing requirements that apply specifically to specific products. For example, in the case of sour milk products, the legislation determines the number of living microorganisms that must be present in the product, in the case of butter, the amount of fat in the product is determined, and so on. Food additives may be added to milk products by Regulation (EC) No 258/97 of the European Parliament and the Council. in the case of butter, the amount of fat in the product is determined, etc. Food additives may be added to milk products by Regulation (EC) No 258/97 of the European Parliament and the Council. in the case of butter, the amount of fat in the product is determined, etc. Food additives may be added to milk products by Regulation (EC) No 258/97 of the European Parliament and the Council **1333/2008** [18]. Food additives are substances that are not normally consumed as food as such but are intentionally added to food for technological purposes. Packaging materials must be suitable for use in the food industry. The production of

specific PGI, PDO and TSG products is carried out in such a way that the registered product specification **1151/2012** [19], **668/2014** [20]. Other legislation is listed in the overview tables.

13. Common milk market organization

The common organization of the market in agricultural products is governed by Regulation (EU) No 182/2011 of the European Parliament and the Council **1308/2013** [15]. For example, the regulation defines and catalogs milk and selected dairy products, addresses the contractual arrangements for the supply of milk, the obligations of first-time raw milk buyers, and obliges the Commission to report to the European Parliament on the situation in the dairy market.

Other European Union legislation in this area, which is listed in Table 2, also applies.

Table 2 Legislation for the common organization of the market in milk and milk products.

Prescription number	Name of the regulation
<u>595/2004</u>	Commission Regulation (EC) No 595/2004 of 30 March 2004 laid down detailed rules for the application of Council Regulation (EC) No 1234/2007 1788/2003 establishing a levy on the milk and milk products sector.
<u>565/2013</u>	Commission Implementing Regulation (EU) No 565/2013 of 18 June 2013 amending Regulations (EC) No 1731/2006, (ES) No 273/2008, (ES) No 566/2008, (ES) No 867/2008, (ES) No 606/2009 and Implementing Regulations (EU) No 543/2011 and (EU) Amending Regulation (EC) No 1333/2011 as regards the notification obligation under the common organization of agricultural markets and repealing Regulation (EC) No 491/2007.
<u>1307/2013</u>	Regulation (EU) No 182/2011 of the European Parliament and of the Council Commission Regulation (EC) No 1307/2013 of 17 December 2013 laid down rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 1257/1999 637/2008, and Council Regulation (EC) No 73/2009.
<u>1308/2013</u>	Regulation (EU) No 182/2011 of the European Parliament and of the Council Regulation (EC) No 1308/2013 of 17 December 2013 establishing a common organization of the markets in agricultural products and repealing Council Regulations (EEC) No 2454/93 922/72, (EHS) No 234/79, (ES) No 1037/2001, and (ES) No 1234/2007.
<u>906/2014</u>	Commission Delegated Regulation (EU) No 906/2014 of the European Parliament and of the Council of 11 March 2014 1306/2013 as regards public intervention expenditure.
<u>907/2014</u>	Commission Delegated Regulation (EU) No 907/2014 of the European Parliament and of the Council of 11 March 2014 1306/2013 as regards paying agencies and other bodies, financial management, clearance of accounts, guarantees, and use of the euro
<u>1097/2014</u>	Commission Implementing Regulation (EU) No 1097/2014 of 17 October 2014 amending Regulation (EU) No 479/2010 on notifications by the Member States in the milk and milk products sector.
<u>2016/ 1238</u>	Commission Delegated Regulation (EU) 2016/1238 of 18 May 2016 supplementing Regulation (EU) No 182/2011 of the European Parliament and the Council 1308/2013 as regards public intervention and private storage aid.
<u>2016/ 1240</u>	Commission Implementing Regulation (EU) 2016/1240 of 18 May 2016 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and the Council about public intervention and aid for private storage
<u>2016/2080</u>	Commission Implementing Regulation (EU) 2016/2080 of 25 November 2016 opened the sale of skimmed milk powder by a tendering procedure.
<u>2017/1185</u>	Commission Implementing Regulation (EU) No 2017/1185 of 20 April 2017 laying down detailed rules for the application of Regulation (EU) No 182/2011 of the European Parliament and the Council 1307/2013 and (EU) No 1308/2013 as regards the provision of information and the submission of documents to the Commission and amending and repealing several Commission Regulations.
<u>2017/40</u>	Commission Delegated Regulation (EU) 2017/40 of 3 November 2016 supplementing Regulation (EU) No 182/2011 of the European Parliament and the Council Amending Commission

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	Implementing Regulation (EU) No 1308/2013 as regards Union aid for the supply of fruit and vegetables, bananas and milk in educational establishments and amending Commission Implementing Regulation (EU) No 1308/2013 907/2014.
<u>2018/147</u>	Council Regulation (EU) 2018/147 of 29 January 2018 amending Regulation (EU) No 182/2011 1370/2013 as regards the quantitative limit for the purchase of skimmed milk powder.
<u>2018/149</u>	Commission Delegated Regulation (EU) 2018/149 of 15 November 2017 amending Commission Delegated Regulation (EU) 2016/1238 as regards compositional and quality requirements for milk and milk products eligible for public intervention and private storage aid.
<u>2018/150</u>	Commission Implementing Regulation (EU) 2018/150 of 30 January 2018 amending Implementing Regulation (EU) 2016/1240 as regards methods for analyzing and evaluating the quality of milk and milk products eligible for public intervention and private storage aid.
<u>2018/150</u>	Commission Implementing Regulation (EU) 2018/150 of 30 January 2018 amending Implementing Regulation (EU) 2016/1240 as regards methods for analyzing and evaluating the quality of milk and milk products eligible for public intervention and private storage aid.
<u>2018/1879</u>	Commission Implementing Regulation (EU) 2018/1879 of 29 November 2018 amending Implementing Regulation (EU) 2016/2080 as regards the date of storage of skimmed-milk powder sold under a tendering procedure.
<u>2018/765</u>	Commission Implementing Regulation (EU) 2018/765 of 23 May 2018 amending Implementing Regulation (EU) 2016/2080 as regards the date of storage of skimmed-milk powder sold under a tendering procedure.
<u>2020/532</u>	Commission Implementing Regulation (EU) 2020/532 of 16 April 2020 laying down derogations from Implementing Regulations (EU) No 809/2014, (EU) No 180/2014, (EU) No 181/2014, (EU) 2017/892, (EU) 2016/1150, (EU) 2018/274, (EU) 2017/39, (EU) 2015/1368, and (EU) 2016/1240, as regards certain administrative and on-the-spot checks applicable under the common agricultural policy.
<u>2020/591</u>	Commission Delegated Regulation (EU) 2020/591 of 30 April 2020 established a temporary special aid scheme for the private storage of certain cheeses and fixed the amount of aid in advance.
<u>2020/ 597</u>	Commission Implementing Regulation (EU) 2020/597 of 30 April 2020 granting private storage aid for butter and fixing in advance the amount of aid.
<u>2020/598</u>	Commission Implementing Regulation (EU) 2020/598 of 30 April 2020 granting private storage aid for skimmed-milk powder and fixing the amount of aid in advance.
<u>2020/599</u>	Commission Implementing Regulation (EU) 2020/599 of 30 April 2020 authorizing the conclusion of agreements and decisions on production planning in the milk and milk products sector.
<u>2020/600</u>	Commission Implementing Regulation (EU) 2020/600 of 30 April 2020 laying down derogations from Implementing Regulation (EU) 2017/892, Implementing Regulation (EU) 2016/1150, Implementing Regulation (EU) No 615/2014, Implementing Regulation (EU) 2015/1368 and Implementing Regulation (EU) 2017/39 as regards certain measures to address the COVID-19 pandemic crisis.
<u>2020/760</u>	Commission Delegated Regulation (EU) 2020/760 of 17 December 2019 supplementing Regulation (EU) No 182/2011 of the European Parliament and of the Council amending Regulation (EC) No 1308/2013 as regards the rules for administering import and export tariff quotas subject to licenses and supplementing Regulation (EU) No 1308/2013 of the European Parliament and the Council 1306/2013 as regards the lodging of security in the administration of tariff quotas.
<u>2020/1471</u>	Commission Implementing Regulation (EU) 2020/1471 of 12 October 2020 fixing the interest rates to be used for calculating the costs of financing intervention measures comprising buying-in, storage, and disposal for the EAGF 2021 accounting period.

14. Food hygiene legislation

In the field of food hygiene, the legislation is listed in Table 3. The old EU legislation [35], was replaced by new legislation in 2004 [34]. There are several regulations solving the food hygiene in the EU.

Table 3 Food hygiene legislation.

Prescription number	Name of the regulation
<u>2020/2235</u>	Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down detailed rules for the application of Regulations (EU) 2016/429 of the European Parliament and the Council and (EU) 2017/625 as regards model animal health certificates, model official certificates, and model animal health certificates / official certificates for the entry and movement of consignments of certain categories of animals and goods into the Union, the official certification of such certificates and repealing Regulation (EC) No 1774/2002; Implementing Regulations (EU) No 599/2004 636/2014 and (EU) 2019/628, Directive 98/68 / EC and Decisions 2000/572 / EC, 2003/779 / EC, and 2007/240 / EC.
<u>2019/627</u>	Commission Implementing Regulation (EU) 2019/627 laying down uniform practical arrangements for carrying out official controls on products of animal origin intended for human consumption by Regulation (EU) 2017/625 of the European Parliament and the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls.
<u>2019/1139</u>	Commission Implementing Regulation (EU) 2019/1139 of 3 July 2019 amending Regulation (EC) No Amending Regulation (EC) No 2074/2005 as regards official controls on the food of animal origin related to food chain information and fishery products and reference to recognized testing methods for the detection of marine biotoxins and testing methods for raw and heat-treated cow's milk.
<u>2017/625</u>	Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls.
<u>16/2012</u>	Commission Regulation (EU) No Amending Annex II to Regulation (EC) No 16/2011 of the European Parliament and of the Council 853/2004 as regards requirements for frozen foodstuffs of animal origin intended for human consumption.
<u>931/2011</u>	Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on traceability requirements laid down in Regulation (EC) No 931/2011 of the European Parliament and the Council 178/2002 about the food of animal origin.
<u>765/2006</u>	Commission Decision 2006/765/EC repealing certain implementing rules concerning food hygiene and health conditions for the production and placing on the market certain products of animal origin intended for human consumption.
<u>2074/2005</u>	Commission Regulation laying down implementing measures for certain products under Regulation (EC) No 1234/2007 853/2004 and for the organization of official controls under Regulations (EC) No 854/2004 and 882/2004 derogating from Regulation (EC) No Amending Regulation (EC) No 852/2004 853/2004 and 854/2004.
<u>2073/2005</u>	Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.
<u>853/2004</u>	Regulation (EC) No Laying down specific hygiene rules for food of animal origin.
<u>852/2004</u>	Regulation (EC) No 852/2004 on food hygiene. Commission Communication on the implementation of food safety management systems taking into account essential requirements programs (NCPs) and HACCP-based procedures, including simplification/flexibility in implementation for certain food business operators. <i>Codex Alimentarius</i> standards - Regulation (EC) No 852/2004 on food hygiene takes into account the international food safety standards contained in the <i>Codex Alimentarius</i> . The European Commission's guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 on food hygiene sets out certain standards developed by the <i>Codex Alimentarius</i> .
<u>178/2002</u>	Regulation (EC) No 178/2002 laid down the general principles and requirements of food law, and guidelines for the implementation of Articles 11, 12, 16, 17, 18, 19, and 20.
<u>315/93</u>	Council Regulation (EEC) No Council Regulation (EEC) No 315/93 of 8 February 1993 laid down Community procedures for contaminants in food.
<u>1881/2006</u>	Commission Regulation (EC) No Regulation (EC) No 1881/2006 of 19 December 2006 set maximum levels for certain contaminants in foodstuffs.

15. Products not intended for human consumption

Dairy companies produce food waste and the EU has adopted health rules concerning animal by-products and derived products not intended for human consumption which should be taken into account (Table 4).

Table 4 Additional legislation for the dairy sector.

Prescription number	Name of the legislation
<u>1069/2009</u>	Regulation (EC) No 1/2003 of the European Parliament and the Council Commission Regulation (EC) No 1069/2009 of 21 October 2009 laying down health rules concerning animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1829/2003 1774/2002.

16. Legislation for PGI, PDO, and TSG

Products with a protected geographical indication, a protected designation of origin, and guaranteed traditional specialties are marked with quality marks by EU legislation (Table 5). The specific labeling of traditional products is important for EU customers [31].

Table 5 Legislation for PGIs, PDOs, TSGs.

Prescription number	Name of the legislation
<u>1151/2012</u>	Regulation (EU) No 182/2011 of the European Parliament and of the Council 1151/2012 of 21 November 2012 quality systems for agricultural products and foodstuffs.
<u>668/2014</u>	Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 182/2011 of the European Parliament and of the Council 1151/2012 on quality systems for agricultural products and foodstuffs.



Figure 2 Example of the European PDO, PGI and TSG marks. Note: Protected geographical indication (PGI); Protected designation of origin (PDO); and Traditional speciality guaranteed (TSG).

17. Organic agricultural production

Since 1 January 2022, Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 is the applicable legislative act, also known as the basic act, laying down the rules on organic production and labelling of organic products, repealing and replacing Council Regulation (EC) No 834/2007 of 28 June 2007. The new regulation provides for transitional periods for the implementation of certain new provisions, in particular on trade. Please refer to section 2 of Chapter IX of Regulation (EU) 2018/848, where provisions under previous Council Regulation (EC) No 834/2007 and Commission Regulation (EC) No 889/2008 may apply for a limited period.

It is on the basis of Regulation (EU) 2018/848 that the Commission adopts further detailed secondary legal acts.

The types of secondary legal acts are the following:

delegated acts, also known as Commission Delegated Regulations, which are acts of general application to supplement (“Commission Delegated Regulation supplementing”) or amend (“Commission Delegated Regulation amending”) certain non-essential (in the sense of complementary) elements of the legislative act; implementing acts, also known as Commission Implementing Regulations, which are used where uniform conditions for implementation are needed.

Delegated acts amending the basic act are progressively incorporated into the so-called “consolidated” text of the legislative act and become part of it. Please note that the consolidated version of Regulation (EU) **2018/848** is made available only for informative purposes, but has no legal effect. The authentic versions of the relevant acts, including their preambles, are those published in the Official Journal of the European Union

Table 6 Legislation for organic farming.

Prescription number	Name of the legislation
<u>834/2007</u>	Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labeling of organic products and repealing Regulation (EEC) No 2454/93, 2092/91.
<u>889/2008</u>	Commission Regulation (EC) No 889/2008 of 5 September 2008 laid down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labeling of organic products about organic production, labeling, and control.
<u>848/2018</u>	Regulation (EU) No 2018/848 of the European Parliament and of the council of 30 May 2018 on organic production and labeling of organic products and repealing council regulation (EC) No 1782/2003, 834/2007.
<u>2021/1165</u>	Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorizing certain lists of products and substances for use in organic farming.
<u>2021/1378</u>	Commission Implementing Regulation (EU) No 2021/1378 of 19 August 2021 laying down certain rules concerning the certificate issued to operators, groups of operators, and exporters in third countries involved in imports of organic products and products from conversion into the Union, establishing a list of recognized public inspection bodies and private inspection bodies by Regulation (EU) No 2018/848 of the European Parliament and the Council.
<u>2021/2119</u>	Commission Implementing Regulation (EU) No 2021/2119 of 1 December 2021 laying down detailed rules concerning certain records and declarations required of operators and groups of operators and the technical means for issuing certificates by regulation (EU) 2018 of the European Parliament and the Council / 848 and amending Commission Implementing Regulation (EU) 2021/1378 as regards the certification of operators, groups of operators and exporters in third countries.
<u>2021/2307</u>	Commission Implementing Regulation (EU) No 2021/2307 of 21 October 2021 laying down rules concerning the documents and notifications required for organic products and products of conversion intended for import into the Union.
<u>2021/2325</u>	Commission Implementing Regulation (EU) No 2021/2325 of 16 December 2021 establishing, according to Regulation (EU) No 2018/848 of the European Parliament and the council, the list of third countries and the list of public inspection bodies and private inspection bodies recognized under article 33 (2). 2 a 3 Council Regulation (EC) No 834/2007 to import organic products into the Union.
<u>2020/427</u>	Delegated Regulation (EU) 2020/427 of 13 January 2020 amending Annex II to Regulation (EU) 2018/848 on certain detailed production rules for organic products (OJ L 87, 23.3.2020)
<u>2020/1794</u>	Delegated Regulation (EU) 2020/1794 of 16 September 2020 amending Part I of Annex II to Regulation (EU) 2018/848 on the use of in-conversion and non-organic plant reproductive material (OJ L 402, 1.12.2020)
<u>2021/642</u>	Delegated Regulation (EU) 2021/642 of 30 October 2020 amending Annex III to Regulation (EU) 2018/848 on certain information to provide on the labelling of organic products (OJ L 133, 20.4.2021)
<u>2021/716</u>	Delegated Regulation (EU) 2021/716 of 9 February 2021 amending Annex II to Regulation (EU) 2018/848 on organic production rules on sprouted seeds and chicory heads, on feed for certain aquaculture animals and on aquaculture parasite treatments (OJ L 151, 3.5.2021).

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<u>2022/474</u>	Delegated Regulation (EU) 2022/474 of 17 January 2022 amending Annex II to Regulation (EU) 2018/848 on specific requirements for the production and use of non-organic, in-conversion and organic seedlings and other plant reproductive material.
<u>2020/2146</u>	Delegated Regulation (EU) 2020/2146 of 24 September 2020 supplementing Regulation (EU) 2018/848 on exceptional production rules in organic production (OJ L 428, 18.12.2020)
<u>2021/1189</u>	Delegated Regulation (EU) 2021/1189 of 7 May 2021 supplementing Regulation (EU) 2018/848 on the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species (OJ L 258, 20.7.2021)
<u>2020/464</u>	Implementing Regulation (EU) 2020/464 of 26 March 2020 laying down certain rules for the application of Regulation (EU) 2018/848 on the documents needed for the retroactive recognition of periods for the purpose of conversion, the production of organic products and information to be provided by EU countries (OJ L 98, 31.3.2020)
<u>2021/1165</u>	Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists (OJ L 253, 16.7.2021)
<u>2021/715</u>	Delegated Regulation (EU) 2021/715 of 20 January 2021 amending Regulation (EU) 2018/848 on the requirements for groups of operators (OJ L 151, 3.5.2021)
<u>2021/1006</u>	Delegated Regulation (EU) 2021/1006 of 12 April 2021 amending Regulation (EU) 2018/848 on the model of certificate attesting compliance with the rules on organic production (OJ L 222, 22.6.2021)
<u>2021/1691</u>	Delegated Regulation (EU) 2021/1691 of 22 September 2021 amending Annex II to Regulation (EU) 2018/848 on the requirements for records keeping from operators in organic production (OJ L 334, 22.9.2021)
<u>2021/771</u>	Delegated Regulation (EU) 2021/771 of 21 January 2021 supplementing Regulation (EU) 2018/848 laying down specific criteria and conditions for the checks of documentary accounts in the framework of official controls in organic production and the official controls of groups of operators (OJ L 165, 11.5.2021)
<u>2021/2304</u>	Delegated Regulation (EU) 2021/2304 of 18 October 2021 supplementing Regulation (EU) 2018/848 with rules on the issuance of complementary certificates certifying the non-use of antibiotics in organic production of animal products for the purpose of export (OJ L 461, 27.12.2021)
<u>2021/279</u>	Implementing Regulation (EU) 2021/279 of 22 February 2021 laying down detailed rules for implementation of Regulation (EU) 2018/848 on controls and other measures ensuring traceability and compliance in organic production and the labelling of organic products (OJ L 62, 23.2.2021)
<u>2021/1935</u>	Implementing Regulation (EU) 2021/1935 of 8 November 2021 amending Implementing Regulation (EU) 2019/723 on the information and data on organic production and labelling of organic products to be submitted by means of the standard model (OJ L 396, 10.11.2021, p. 17–26)
<u>2021/2119</u>	Implementing Regulation (EU) 2021/2119 of 1 December 2021 on records and declarations required from operators and groups of operators and on the technical means for the issuance of certificates in accordance with Regulation (EU) 2018/848 and amending Implementing Regulation (EU) 2021/1378 of 19 August 2021 on the issuance of the certificate for operators, groups of operators and exporters in third countries (OJ L 430, 2.12.2021)
<u>2021/1697</u>	Delegated Regulation (EU) 2021/1697 of 13 July 2021 amending Regulation (EU) 2018/848 on the criteria for the recognition of control authorities and control bodies competent to carry out controls on organic products in third countries, and on the withdrawal of their recognition (OJ L 336, 23.9.2021)
<u>2021/1698</u>	Delegated Regulation (EU) 2021/1698 of the 13 July 2021 supplementing Regulation (EU) 2018/848 with procedural requirements for the recognition of control authorities and control bodies that are competent to carry out controls on operators and groups of operators certified organic, and on organic products in third countries, and with rules on their supervision and the controls and other actions to be performed by those control authorities and control bodies (OJ L 336, 23.9.2021)
<u>2021/1342</u>	Delegated Regulation (EU) 2021/1342 of 27 May 2021 supplementing Regulation (EU) 2018/848 with rules on the information to be sent by third countries and by control authorities and control bodies for the purpose of supervision of their recognition under Article 33(2) and (3)

	of Regulation (EC) No 834/2007 of 28 June 2007 for imported organic products and the measures to be taken in the exercise of that supervision (OJ L 292, 16.8.2021)
<u>2021/2305</u>	Delegated Regulation (EU) 2021/2305 of 21 October 2021 supplementing Regulation (EU) 2017/625 with rules on the cases where and conditions under which organic products and in-conversion products are exempted from official controls at border control posts, the place of official controls for such products and amending Commission Delegated Regulations (EU) 2019/2023 and (EU) 2019/2124 (OJ L 461, 27.12.2021)
<u>2021/2306</u>	Delegated Regulation (EU) 2021/2306 of 21 October supplementing Regulation (EU) 2018/848 with rules on the official controls in respect of consignments of organic products and in-conversion products intended for import into the EU and on the certificate of inspection (OJ L 461, 27.12.2021)
<u>2022/760</u>	Delegated Regulation (EU) 2022/760 of 8 April 2022 amending Delegated Regulation (EU) 2021/2306 as regards the transitional provisions for certificates of inspection issued in Ukraine (OJ L 139, 18.5.2022)
<u>2021/1378</u>	Implementing Regulation (EU) 2021/1378 of 19 August 2021 laying down certain rules in accordance with Regulation (EU) 2018/848 concerning the certificate issued to operators, groups of operators and exporters in third countries involved in the imports of organic and in-conversion products into the EU and establishing the list of recognised control authorities and control bodies for the purpose of compliance (OJ L 297, 20.8.2021)
<u>2021/2307</u>	Implementing Regulation (EU) 2021/2307 of 21 October 2021 on documents and notifications required for organic and in-conversion products intended for import into the EU (OJ L 461, 27.12.2021)
<u>2021/2325</u>	Implementing Regulation (EU) 2021/2325 of 16 December 2021 establishing, pursuant to Regulation (EU) 2018/848 the list of third countries and the list of control authorities and control bodies that have been recognised under Article 33(2) and (3) of Regulation (EC) No 834/2007 for the purpose of importing organic products into the EU (OJ L 465, 29.12.2021)



Figure 3 The organic logo.

The European Union organic logo gives a coherent visual identity to organic products produced in the EU. This makes it easier for consumers to identify organic products and helps farmers to market them across the entire EU.

The organic logo can only be used on products that have been certified as organic by an authorised control agency or body. This means that they have fulfilled strict conditions on how they must be produced, processed, transported and stored. The logo can only be used on products when they contain at least 95% organic ingredients and additionally, respect further strict conditions for the remaining 5%. The same ingredient cannot be present in organic and non-organic form.

Next to the EU organic logo, a code number of the control body must be displayed as well as the place where the agricultural raw materials composing the product have been farmed [26].

18 Hygiene manuals, *Codex Alimentarius* standards and ISO standards

Regulation (EC) No **852/2004** [4] of the European Parliament and of the Council on the hygiene of foodstuffs of 29 April 2004, Chapter 1, Article 1 paragraph 1. states that "the guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;" and Chapter III, Article 8 paragraph 4. requires that, "The Member States shall forward to the Commission national guides complying with the requirements of paragraph 3. The Commission shall set up and run a registration system for such guides and make it available to the Member States" [21].

The Codex Alimentarius Commission, established in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and WHO, develops harmonized international food standards, guidelines and codes of practice to protect the health of consumers and ensure fair trade practices in the food trade [22].

ISO Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators [23].

19 Conclusion

The legal regulations of the European Union, hygiene manuals, ISO standards, and *Codex Alimentarius* standards create a framework that regulates the production of milk and dairy products, payment systems for primary producers, contains rules for their safety, and quality, labeling, control, and consumer health protection. These rules apply at all stages of the food chain, in primary production, production, and various forms of sale, including import and export. The main objectives of the legislation include consumer protection, consumer information, free movement of milk and dairy products within the EU, regulation of imports and exports of these products, and establishing a quality system for specific products such as protected label products or organic food.

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