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Comparison of hygiene rules for Grade A Milk Products in the United States and the European Union

The comparison of the US federal milk ordinance with the respective provisions of the EU food law poses some difficulty, because a similarly specific ordinance does not exist in the Community legislation. European law regulates food hygiene by horizontal legislation, which covers all foods and the entire chain of production and marketing, farm to fork. Similarly, animal health aspects are covered by horizontal rules for all products of animal origin. Finally, market order legislation addresses questions of product quality and labeling.

The comparison was undertaken on a basis of a detailed appraisal of the US milk ordinance, and seeking to identify matching elements in the EU Law. Given the relative uniformity of the product category 'milk', its methods and technology of production and processing and also the nature of the hazards involved it is not surprising that these matching elements can generally be found.

However, given the narrower scope of the US milk ordinance, it is conceivable that it provides detailed and specific rules for the inspection, including the frequency of inspection of individual actors in the production chain, such as milk farms, tank trucks, haulers, collectors, processors or retailers. EU provisions rather focus on general principles and objectives for such controls throughout the production chain. A system of Community-wide audits by the Food and Veterinary Office ensures consistent implementation by Competent Authorities in all Member States and at all levels.

Similarly, the US milk ordinance sets detailed provisions for personnel hygiene and defines criteria for imposing and lifting personnel restrictions in case of potential disease. Again, EU law rather defines the objectives and allocates the clear responsibility on all food business operators and authorities to ensure that adequate procedures are implemented and verified to exclude contamination of food with pathogens.

In summary it appears that both, EU and US provisions provide for a very high level of consumer protection via a multitude of measures throughout the milk production chain, which are essentially very similar.

A review of actual inspection guidelines of Member States and personnel hygiene rules may be undertaken by a working group to further substantiate this conclusion. A joint review of audit reports of the Food and Veterinary Office and US inspection services could also be envisaged.

Annex

Comparison of provisions of the US Grade "A" Pasteurized Milk Ordinance (PMO) 2003 with harmonised EU legislation

Terms used in this document are those within Title 21, *Code of Federal Regulations* (CFR) and/or the *Federal Food, Drug, and Cosmetic Act* (FFD&CA) as amended. The Pasteurized Milk Ordinance provides the following, additional definitions:

1 Definitions

Pasteurized Milk Ordinance	Harmonized EU Legislation	Conclusion
Milk: Hoofed mammals milk is the normal lacteal secretion, practically free of colostrums, obtained by the complete milking of one or more healthy, hoofed mammals. This product shall be produced according to the sanitary standards of this Ordinance. A-1. **Abnormal Milk:** Milk that is visibly changed in color, odor and/or texture. A-2. **Undesirable Milk:** Milk that, prior to the milking of the animal, is known to be unsuitable for sale, such as colostrum. A-3. **Contaminated Milk:** Milk that is un-saleable or unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements, or treatment with medicines or insecticides not approved for use on dairy animals by FDA or the Environmental Protection Agency (EPA).	**Regulation 853/2004 (Annex 1)** defines: '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 must come from 'healthy' animals. The exclusion of colostrum is provided for cows milk via the definition of a maximum somatic cell count as follows: Annex III Section IX Chapter I of the same Regulation provides that milk from cows must have somatic cells below 400.000 per ml (rolling geometric mean over 3 months). For other species, see below. The same Chapter provides that raw milk must come from healthy animals "to which no unauthorised substances or products have been administered and that have not undergone illegal treatment … Where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed."	Definitions are similar. The 'healthiness' element is provided in the US definition of 'hoofed animals milk' (see below).
BUTTERMILK: Buttermilk is a fluid product resulting from the manufacture of butter from milk or cream. It contains not less than 8¼ percent of milk solids not fat.	Under EU legislation, milk products, such as butter, buttermilk, whey, cream, casein and others are defined in accordance with CN codes.	EU provisions concerning hygiene fully apply to all Grade A diary products. They also apply to cheeses and other milk products which are not covered by the US

Pasteurized Milk Ordinance	Harmonized EU Legislation	Conclusion
1. Grade "A" Dry Buttermilk 2. Grade "A" Dry Buttermilk Products 3. Concentrated (Condensed) Buttermilk 4. Grade "A" Concentrated (Condensed) and Dry Buttermilk and Buttermilk Products **CONCENTRATED (CONDENSED) MILK:** Unsterilized and unsweetened, resulting from the removal of a considerable portion of the water from the milk, which when combined with potable water in accordance with instructions printed on the container label, results in a product conforming with the milkfat and milk solids not fat levels of milk as defined in this Section. **FROZEN MILK CONCENTRATE:** A composition of milk fat and milk solids not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milk fat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported and sold in the frozen state. **WHEY PRODUCTS:** Whey products mean any fluid product removed from whey; or made by the removal of any constituent from whey; or by the addition of any wholesome substance to whey or parts thereof. **DAIRY FARM:** A dairy farm is any place or premises where one (1) or more lactating animals (cows, goats, sheep, water buffalo, or other hoofed mammal) are kept for milking purposes, and from which a part or all of the milk or milk product(s) is provided, sold or offered for sale to a milk plant, receiving station or transfer station. **GOAT MILK:** Goat milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete	Regulations 1411/71 and 2597/97 ‘laying down additional rules on the common organisation of the market in milk and milk products’ also provide definitions for several products. Methods for the determination of critical parameters such as water, fat or protein content are provided in Commission Regulation 213/2001 laying down detailed rules for the application of Council Regulation 1255/1999 as regards methods for the analysis and quality evaluation of milk and milk products. These definitions of different milk products are important for the allocation of market order interventions, tariffs and quota, but they have generally no relevance for their sanitary status. All diary products fall under the scope of Regulation 853/2004, which defines dairy products as ‘processed products resulting from the processing of raw milk or from the further processing of such processed products.’ The provisions concerning animal health and general hygiene fully apply to all these products; **Regulation 853/2004, Annex I:** «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. General definition of ‘raw milk’ in Annex I to Regulation 853/2004 covers goats milk, but the Regulation provides	milk ordinance. The US milk ordinance contains elements related to market order, which have no bearing as to the sanitary status of the products in question.

Pasteurized Milk Ordinance	Harmonized EU Legislation	Conclusion
milking of one (1) or more healthy goats. Goat milk sold in retail packages shall contain not less than 2½ percent milk fat and not less than 7½ percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include goat milk. **MILK DISTRIBUTOR:** A milk distributor is any person who offers for sale or sells to another any milk or milk products. **MILK PLANT** **MILK PRODUCER** **MILK PRODUCTS:** Milk products include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk and milk products, concentrated (condensed) milk, concentrated (condensed) milk products, concentrated (condensed) and dry milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, buttermilk products, whey, whey products, cultured milk, cultured reduced fat or lowfat milk, cultured nonfat (skim) milk, yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, acidified nonfat (skim) milk, low-sodium milk, low-sodium reduced fat or lowfat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced reduced fat or lowfat milk, lactose-reduced nonfat (skim) milk, aseptically processed and packaged milk and milk products as defined in this Section, milk, reduced fat, lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein,	no limit values for somatic cells to exclude colostrums from goats All food business operators in the production and retailing chain of milk and dairy products must comply with Regulation 852 and 853/2004. Regulation 853/2004 defines: 'Milk production holding' as an establishment where one or more farmed animals are kept to produce milk with a view to placing it on the market as food. 'Dairy products' means processed products resulting from the processing of raw milk or from the further processing of such processed products. All these products fall under the scope of Regulation 853/2004, which includes, consequently, also dry milk products, cheeses, ice creams and infant formulae, as far as they are made from milk. As far as foods contain ingredients derived from milk, these ingredients must be produced and handled in full compliance with the Regulation. For infant formulae, specific, vertical legislation exists, in addition.	The definition of 'diary products' in the EU hygiene legislation covers all Grade A milk products.

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vitamin or mineral fortification of milk products defined herein. Milk products also include those dairy foods made by modifying the federally standardized products listed in this Section in accordance with 21 CFR 130.10-Requirements for foods named by use of a nutrient content claim and a standardized term. This Definition shall include those milk and milk products, as defined herein, which have been aseptically processed and then packaged. Milk and milk products which have been retort processed after packaging or which have been concentrated (condensed) or dried are included in this Definition only if they are used as an ingredient to produce any milk or milk product defined herein or if they are labeled as Grade "A" as described in Section 4. This definition is not intended to include dietary products (except as defined herein), infant formula, ice cream or other frozen desserts, butter or cheese.		
OFFICIAL LABORATORY: An official laboratory is a biological, chemical or physical laboratory, which is under the direct supervision of the Regulatory Agency. **OFFICIALLY DESIGNATED LABORATORY:** An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory **Agency** for the examination of producer samples of Grade "A" raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues and bacterial limits.	Regulation 882/2004 on Official Food and Feed Controls defines the role of official laboratories. It provides that all laboratories must be accredited according to international standards (Article 14). National and Community Reference Laboratories must be designated, in addition, to coordinate the work and to ensure high, consistent performance (Articles 32 and 33). Regulation 2076/2005 allows some transitional derogations (Article 18).	
PASTEURIZATION: The terms "pasteurization", "pasteurized" and similar terms **shall** mean the process of heating every particle of milk or milk product, in properly designed and operated equipment, to one (1) of the	Regulation 853/2004 provides Pasteurisation is achieved by a treatment involving: (i) a high temperature for a short time (at least 72 °C for 15 seconds);	

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temperatures given in the following chart and held continuously at or above that temperature for at least the corresponding specified time: **Temperature** **Time** 63°C (145°F)* 30 minutes 72°C (161°F)* 15 seconds 89°C (191°F) 1.0 second 90°C (194°F) 0.5 seconds 94°C (201°F) 0.1 seconds 96°C (204°F) 0.05 seconds 100°C (212°F) 0.01 seconds *If the fat content of the milk product is ten percent (10%) or more, or if it contains added sweeteners, or if it is concentrated (condensed), the specified temperature shall be increased by 3°C (5°F). Provided, that eggnog shall be heated to at least the following temperature and time specifications: **Temperature** **Time** 69°C (155°F) 30 minutes 80°C (175°F) 25 seconds 83°C (180°F) 15 seconds Provided further, that nothing shall be construed as barring any other pasteurization process, which has been recognized by FDA to be equally efficient and which is approved by the Regulatory Agency.	15 seconds); (ii) a low temperature for a long time (at least 63 °C for 30 minutes); or (iii) 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. There are no specific provisions for eggnog or products with high fat content, but the desired end point (i.e. negative phosphatase test) is specified	
RECONSTITUTED OR RECOMBINED MILK AND MILK PRODUCTS: Reconstituted or recombined milk and/or milk products shall mean milk or milk products defined in this Section which result from reconstituting or recombining of milk constituents with potable water when appropriate	Regulation 853/2004 covers this category of products:	
SANITIZATION: Is the application of any effective method or substance to properly cleaned surfaces for the	Annex II to Regulation 852/2004 provides detailed requirements for the cleaning and disinfection of surfaces	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Conclusion
destruction of pathogens, and other microorganisms, as far as is practicable. Such treatment shall not adversely affect the equipment, the milk and/or milk product, or the health of consumers, and shall be acceptable to the Regulatory Agency.	and equipment.	
SHEEP MILK: Sheep milk is the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include sheep	The general definition of 'raw milk' in Annex I to Regulation 853/2004 covers sheep milk, but it provides no limit values for somatic cells to exclude colostrum.	
ULTRA-PASTEURIZATION (UP): The term "Ultra-Pasteurization", when used to describe a dairy product, means that such product shall have been thermally processed at or above 138°C (280°F) for at least two (2) seconds, either before or after packaging, so as to produce a product, which has an extended shelf-life under refrigerated conditions. (Refer to 21 CFR 131.3) milk.	**Regulation 853/2004 provides:** Ultra high temperature (UHT) treatment is achieved by a treatment: (i) 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 micro-organisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature; and (ii) sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30 °C in closed containers or for 7 days at 55 °C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.'	
WATER BUFFALO MILK: Water buffalo milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy water buffalo. Water buffalo milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include water buffalo milk.	The general definition of 'raw milk' in Annex I to Regulation 853/2004 covers sheep milk, but it provides no limit values for somatic cells to exclude colostrum.	

2 Adulterated or Misbranded Milk or Milk Products

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General Provisions No person shall, … produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product, which is adulterated or misbranded. Provided, that in an emergency, the sale of pasteurized milk and milk products, which do not fully meet the requirements of this *Ordinance*, may be authorized by the Regulatory Agency. Any adulterated or misbranded milk or milk products, may be impounded by the Regulatory Agency and disposed of in accordance with applicable laws or regulations.	Several elements in the EU food law provide the same, general obligation throughout the production and distribution chain of all foods, including milk products. **The General Food Law laid down in Regulation 178/2002 provides:** Article 14 - Food safety requirements 1. Food shall not be placed on the market if it is unsafe. 2. Food shall be deemed to be unsafe if it is considered to be: (a) injurious to health; (b) unfit for human consumption … Article 16 - Presentation … the labelling, advertising and presentation of food … and the information which is made available about them through whatever medium, shall not mislead consumers. Article 17 – Responsibilities Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met. Article 19 - Withdrawal If a food business operator considers or has	All elements of the general provisions in the milk ordinance are addressed by EU provisions. The EU law allocates clear rules and responsibilities throughout the food chain. It ensures seamless inspections and controls for enforcement and provides adequate powers to allow regulatory action. The Rapid Alert System ensures the undisturbed flow of information in the Single Market from local authorities to all Member States and the Commission.

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	reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market … and inform the competent authorities thereof. Article 50 - Rapid Alert System 1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the European Food Safety Authority. … 2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system. … 3. … Member States shall immediately notify the Commission under the rapid alert system of: (a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action … **Regulation 852/2004 on the hygiene of food** provides more specific rules. Article 4 - General and specific requirements Food business operators carrying out primary production	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
	or any stage of production, processing and distribution of food … shall comply with the general hygiene provisions and any specific requirements provided for in Regulation (EC) No 853/2004. **Regulation 882/2004 on official food and feed control** provides in Article 54 - Action in the case of non-compliance: When the competent authority identifies non-compliance, it shall take action to ensure that the food business operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and the food business operator's past record with regard to non-compliance.	

3 Permits

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
General Provisions: It shall be unlawful for any person who does not possess a **permit from the Regulatory Agency**... to manufacture, bring into, send into or receive … for sale, or to sell, or offer for sale therein or to have in storage any milk or milk products, defined in this *Ordinance*. Provided, that grocery stores, restaurants, soda fountains and similar establishments where milk or milk products are served or sold at retail, but not processed may be **exempt from the requirements** of this Section. Provided further, that brokers, agents, and distributors representing, buying from, and/or selling condensed and dry milk products from or to a milk plant having a valid permit are not required to have a permit. Only a person who complies with the requirements of this *Ordinance* shall be entitled to receive and retain such a permit. … Permits shall not be transferable with respect to persons and/or locations. **The Regulatory Agency shall suspend such permit**, whenever it has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of this *Ordinance*; or whenever the permit holder has interfered with the Regulatory Agency in the performance of its duties.	The EU hygiene legislation foresees a system of notification and authorization of businesses depending from the risks involved. Authorization can only be granted after on-site inspection. **Regulation 852/2004** applies to all food intended for human consumption. Article 6 - Registration and approval Every food business operator shall **notify** the appropriate competent authority … of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the **registration** of each such establishment. Food business operators shall ensure that establishments are **approved** by the competent authority, following at least one on-site visit, when approval is required (a) under the national law or (b) under Regulation (EC) No 853/2004. **Regulation 853/2004** applies to all foods of animal origin intended for human consumption, i.e. to milk products. Article 4 - Registration and approval of establishments 1. Food business operators shall place	The EU hygiene rules make no difference between different milk products (such as condensed or dry milk product). All products intended for human consumption are to be handled under the same rules, which are equivalent to the US milk ordinance for 'Grade A' milk products. Products not intended for human consumption are regulated under Regulation 1774/2002. The general provisions and criteria for the approval of establishments in the food chain of milk products are very similar in the EU and the US. Also the provisions in case of non-compliance are equivalent. The US milk ordinance includes detailed provisions for the reinstatement of a suspended permit, which is not the case in the harmonized EU law. This difference has no bearing on the sanitary status of a milk product put on the market.

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… It shall be unlawful for any person to manufacture in a milk plant under a permit for Grade "A" condensed or dry milk products …. any condensed and dry milk products which do not meet the requirements of this *Ordinance* for Grade "A" condensed or dry milk products without a permit from the Regulatory Authority. **ISSUANCE OF PERMITS:** Every milk producer, milk distributor, bulk milk hauler/sampler, … and each milk plant, receiving station, …milk tank truck cleaning facility operator shall hold a valid permit. … Grocery stores, restaurants, soda fountains and similar establishments where milk and milk products are served or sold at retail, but not processed, may be exempt from the requirements of this Section. The manufacture of **ungraded products for other**	products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments: (a) 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 (b) that the competent authority has **registered** or, where required in accordance with paragraph 2, approved. 2. … establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has **approved** them, with the exception of establishments carrying out only: (a) primary production; (b) transport operations; (c) the storage of products not requiring temperature-controlled storage conditions; or (d) retail operations …. 3 .An establishment subject to approval in accordance with paragraph 2 shall not operate unless the competent authority has…. (a) granted the establishment **approval to operate following an on-site visit;** Milk products NOT intended for human consumption are under **Regulation 1774/2002** on animal by-products not	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
uses in milk plants operating under a permit for the manufacture of Grade "A" condensed and dry milk products is allowed under conditions specified in Section 7 of this *Ordinance* and whereby such products are processed, packaged, and stored separately. In such cases, a second permit is required, which is issued with the understanding that ungraded products will be handled in such a manner so as to avoid confusion with the Grade "A" production. **SUSPENSION OF PERMIT:** When any requirement(s) of this *Ordinance* is violated, the permit holder is subject to the suspension of their permit. 1. The Regulatory Agency may forego suspension of the permit, provided the milk or milk product in violation is not sold or offered for sale as Grade "A" milk or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk or milk product in violation is not sold or offered for sale as Grade "A" milk or milk product. … **HEARINGS:** If a State Administrative Procedure Act (APA), which provides procedures for administrative hearings and judicial review of administrative determinations, is available, the APA shall be made applicable by reference to the hearings provided for in the *Ordinance*. If such APA is not available, appropriate procedures, including	intended for human consumption. Generally, products not intended for human consumption must not be processed in the same establishments as food. Also these establishments for animal by-products operate under an authorization regime. **Regulation 882/2004 on official food and feed control** Article 54 - Action in the case of non-compliance: 1. When the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the noncompliance and that operator's past record with regard to non-compliance. 2. Such action shall include, where appropriate, the following measures: (a) the imposition of sanitation procedures or any other action deemed necessary to ensure the safety of feed or food or compliance with feed or food law, animal health or animal welfare rules; (b) the restriction or prohibition of the placing on the market, import or export of feed, food or animals; (c) monitoring and, if necessary, ordering the recall, withdrawal and/or destruction of	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
provision for notice, hearing officer, their authority, record of hearing, rules of evidence and court review shall be established by the appropriate authority. **REINSTATEMENT OF PERMITS:** Any permit holder whose permit has been suspended may make written application for the reinstatement of their permit. When the permit suspension has been due to a violation of any of the bacterial, coliform or cooling temperature standards, the Regulatory Agency, within one (1) week after the receipt of notification for reinstatement of permit, shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. When a permit suspension has been due to a violation of the somatic cell count standard, the Regulatory Agency may issue a temporary permit whenever a resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section 7. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period and the Regulatory Agency shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6 of this *Ordinance*. Whenever the permit suspension has been due to a violation of a requirement other than bacteriological, coliform, somatic cell count, drug residue test or cooling-temperature standards, the notification shall indicate that the violation(s) has been corrected. Within one (1) week of the receipt of such	recall, withdrawal and/or destruction of feed or food; (d) the authorisation to use feed or food for purposes other than those for which they were originally intended; (e) the suspension of operation or closure of all or part of the business concerned for an appropriate period of time; (f) the suspension or withdrawal of the establishment's approval; … (h) any other measure the competent authority deems appropriate. 3. The competent authority shall provide the operator concerned, or a representative, with: (a) written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision; and (b) information on rights of appeal against such decisions and on the applicable procedure and time limits.	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
notification, the Regulatory Agency shall make an inspection/audit of the applicant's facility, and as many additional inspections/audits thereafter as are deemed necessary, to determine that the applicant's facility is complying with the requirements. When the findings justify, the permit shall be reinstated. When a permit suspension has been due to a positive drug residue, the permit shall be reinstated in accordance with the provisions of Appendix N.		

4 Labeling

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
All bottles, containers and packages containing milk or milk products defined in Section 1 of this *Ordinance* shall be labelled in accordance with the applicable requirements of the FFD&CA, the *Nutrition Labelling and Education Act* (NLEA) of 1990, and regulations developed there under, the CFR, and in addition, shall comply with applicable requirements of this Section as follows: All bottles, containers and packages containing milk or milk products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, shall be conspicuously marked with: 1. The identity of the milk plant 2. The words "keep refrigerated after opening" 3. The common name of the hoofed mammal producing the milk shall precede the name of the milk or milk product when the product is or is made from other than cattle's milk. 4. The words "Grade "A"" on the exterior surface. … **IDENTITY LABELING:** "Identity", as used in this Section, is defined as the name and address or permit number of the milk plant. It is recommended that the voluntary national uniform coding system … be adopted in order to provide a uniform system of codes throughout the country. In cases where several milk plants are operated by one firm, the common firm name may be utilized on	The General Food Law in **Regulation 178/2002** provides in **Article 16 - Presentation** Without prejudice to more specific provisions of food law, the labeling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers. **Regulation 853/2004** **Article 5 - Health and identification marking** 1. Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has … an identification mark applied. 2. Food business operators may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with this Regulation. **Annex II provides the following on identification Marking**	Some of the provisions of the US milk ordinance are covered by marketing order legislation, others fall under the EU hygiene rules or labeling rules for food. Provisions relevant for public health, i.e. those concerning identification and traceability, storage stability and handling instructions for consumers are very similar. It is unclear whether EU law requires the sealing of trucks used for milk. Traceability rules laid down in Article 18 of the General Food Law (Regulation 178/2002) ensure that each shipment can be traced back throughout the food production chain.

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milk bottles, containers and packages. Provided, that the location of the milk plant at which the contents were pasteurized, ultra-pasteurized, aseptically processed, condensed and/or dried is also shown, either directly or by a code. **MISLEADING LABELS:** The Regulatory Agency shall not permit the use of any misleading marks, words or endorsements upon the label. All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents. Milk tank trucks transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station are required to be marked with the name and address of the milk plant or hauler and shall be sealed; in addition, for each such shipment, a shipping statement shall be prepared containing at least the following information: 1. Shipper's name, address and permit number... 2. Permit identification of hauler... 3. Point of origin of shipment. 4. Tanker identification number. 5. Name of product. 6. Weight of product. 7. Temperature of product when loaded. 8. Date of shipment. 9. Name of supervising Regulatory Agency at the point of origin of shipment. 10. Whether the contents are raw, pasteurized, or in	1. The identification mark must be applied before the product leaves the establishment. 5. The mark must be legible and indelible, and the characters easily decipherable. It must be clearly displayed for the competent authorities. 6. The mark must indicate the name of the country in which the establishment is located … 7. The mark must indicate the approval number of the establishment. 12. In the case of liquid, granulate and powdered products of animal origin carried in bulk, … an identification mark is not necessary if accompanying documentation contains the information specified in points 6, 7 and, where appropriate, 8. **Annex III provides for milk products:** In addition to the requirements of Directive 2000/13/EC ... labeling 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 words «made with raw milk» . **Directive 2000/13** on labeling, presentation and advertising of foodstuffs gives further provisions on storage, identity, weight or volume, and producer.	

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the case of cream, lowfat or skim milk, whether it has been heat-treated. 11. Seal number on inlet, outlet, wash connections and vents. 12. Grade of product. All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer.		

5 Inspection and Controls

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Each dairy farm, milk plant, receiving station, transfer station, milk tank truck cleaning facility whose milk or milk products are intended for consumption …, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances shall be inspected/audited by the Regulatory Agency prior to the issuance of a permit. Following the issuance of a permit, the Regulatory Agency shall: 1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every twelve (12) months. 2. Inspect each bulk milk hauler/sampler's, dairy plant sampler's and industry plant sampler's pickup and sampling procedures at least once every twenty-four (24) months. 3. Inspect each milk plant and receiving station at least once every three (3) months, except that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory	**For milk and milk products,** **Article 4 of Regulation 853/2004 applies:** Article 4 - Registration and approval of establishments 2. Without prejudice to Article 6(3) of Regulation (EC) No 852/2004, establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them in accordance with paragraph 3 of this Article, with the exception of establishments carrying out only: (a) primary production; (b) transport operations; (c) the storage of products not requiring temperature-controlled storage conditions; or (d) retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b). 3. An establishment subject to approval in accordance with paragraph 2 shall not operate unless the competent authority has, in accordance with Regulation (EC) No 854/2004:	As the US ordinance, harmonized legislation in the European Community imposes official inspection and controls on the entire chain of milk production from the dairy farm to the retailer. The scope of the inspections and consequences and sanctions in case of non-compliance are essentially the same under both regulatory rules. Similar to the US rules, controls at the farm level also in Europe may be undertaken by approved veterinarians or designated inspectors of the milk processor and monitored by the competent authority. However, EU legislation does not specify inspection frequencies provided under the US ordinance - dairy farms every 6 months - tank trucks every 12 months - pick up and sampling procedures every 24 months - cleaning facilities every 6 months - milk plants every 3 months However, also under the US ordinance allows deviations from these inspection frequencies if the establishment in question is operating under an approved HACCP quality control program. In the EU, HACCP-based control programs are mandatory for all establishments falling under the scope of Regulation 852/2004 (Article 5) – which includes transport and storage operations. EU law further requires

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minimum frequencies for these regulatory audits are specified in Appendix K. 4. Inspect each milk tank truck cleaning facility and transfer station at least once every six (6) months, except that, for those transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K. 5. Inspect each dairy farm at least once every six (6) months. Should the violation of any requirement … be found to exist on an inspection/audit, a second inspection/audit shall be required after the time deemed necessary to remedy the violation, but not before three (3) days. This second inspection/audit shall be used to determine compliance with the requirements. Any violation of the same requirement on such second inspection/audit, shall call for permit suspension and/or court action or in the case of an industry plant sampler, shall cease the collection of official regulatory samples until successfully re-trained and re-evaluated by the Regulatory Agency. Provided, that when the Regulatory Agency finds that a critical processing element violation involving: 1. Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment;	(a) granted the establishment approval to operate following an on-site visit; or (b) provided the establishment with conditional approval. **The derogation granted for primary production does not exempt dairy farms from official controls:** **Regulation 854/2004** lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. ANNEX IV: RAW MILK AND DAIRY PRODUCTS Chapter I: Control of Milk Production Holdings 1. Animals on milk production holdings must be subject to official controls to verify that the health requirements for raw milk production, and in particular the health status of the animals and the use of veterinary medicinal products, are being complied with. These controls may take place at the occasion of veterinary checks carried out pursuant to Community provisions on animal or public health or animal welfare and may be carried out by an approved veterinarian. 2. If there are grounds for suspecting that the animal health requirements are not being complied with, the general health status of the	that the intensity of official controls of individual establishments shall depend upon the assessed risk and the track record of the operator. In summary it appears that EU and US provisions result in a similar scrutiny of hygiene inspections in all parts of the milk production chain. To substantiate this assessment, a selection of inspection reports from EU and US authorities may be reviewed and discussed in a working group.

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2. A cross-connection exists whereby direct contamination of pasteurized milk or milk product is occurring; or 3. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring. The Regulatory Agency shall take immediate action to prevent further movement of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, the Regulatory Agency shall take prompt action to suspend the permit. Provided, that in the case of milk plants producing aseptically processed milk and milk products, when an inspection of the milk plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to public health and the Regulatory Agency shall take immediate action to suspend the permit of the milk plant for the sale of aseptically processed milk and milk products. The Regulatory Agency shall also make such other inspections and investigations as are necessary for the enforcement of this *Ordinance*. Every permit holder shall, upon the request of the Regulatory Agency, permit access of officially designated persons to all parts of their establishment or facilities to determine compliance with the provisions of this *Ordinance*. A distributor or milk plant operator shall furnish the Regulatory Agency, upon request, for official use only, a true statement of the actual quantities of milk and milk products of	animals is to be checked. 3. Milk production holdings are to undergo official controls to verify that hygiene requirements are being complied with. These official controls may involve inspections and/or the monitoring of controls that professional organisations carry out. If it is shown that the hygiene is inadequate, the competent authority is to verify that appropriate steps are taken to correct the situation. **Transport operators do not require regulatory approval under Reg 853/2004 but they must notify their activity to authorities and are subject to inspection and controls according to the specific criteria in Annex III, Section IX to Regulation 853/2004:** Hygiene on Milk Production Holdings **A. Requirements for premises and 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	

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each grade purchased and sold, a list of all sources of such milk and milk products, records of inspections, tests and pasteurization time and temperature records. It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this *Ordinance*, which is entitled to protection as a trade secret, including information as to the quantity, quality, source or disposition of milk or milk products or results of inspections/audits or tests thereof, to use such information to their own advantage or to reveal it to any unauthorized person. **INSPECTION FREQUENCY:** One (1) milk tank truck inspection every twelve (12) months, or bulk milk hauler/sampler's or industry plant sampler's pickup and sampling procedures inspection each twenty-four (24) months, or one (1) producer, transfer station, or milk tank truck cleaning facility inspection every six (6) months, or one (1) milk plant or receiving station inspection every three (3) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank trucks, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of milk plants at different times of 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** … 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. Chapter II: Control of Raw Milk Upon Collection	

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possible and of milk plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, cleaning and other procedures comply with the requirements of this *Ordinance*. For the purpose of determining the minimum audit frequency for milk plants, receiving stations and transfer stations regulated under the NCIMS HACCP Program the interval shall include the remaining days of the month in which the audit is due. **CERTIFIED INDUSTRY INSPECTION:** The Regulatory Agency may certify industry personnel, with their consent, to carry out cooperatively the provisions of this *Ordinance* with respect to the supervision of dairy farms, bulk milk haul/sampler's pickup and sampling procedures, and/or milk tank trucks. States utilizing certified industry inspections shall have on file and available for review, a written program that describes how the requirements of this *Ordinance* and related documents shall be implemented. Delegation of the inspection and evaluation of bulk milk hauler/sampler's pickup and sampling procedures shall be done by the Sampling Surveillance Officer in accordance with the *Evaluation of Milk Laboratories* (EML). Reports of all inspections conducted by such personnel to determine compliance with the provisions of this *Ordinance* shall be maintained by the industry at a location acceptable to the Regulatory Agency. The Certified Industry Inspector may perform all punitive actions and all inspections for the issuance or reinstatement of	1. The competent authority is to monitor the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III, to Regulation (EC) No 853/2004 (i.e. somatic cell count, plate count, antibiotics and other relevant residue testing). 2. If the food business operator has not corrected the situation within three months of first notifying the competent authority of non-compliance with the criteria with regard to plate count and somatic cell count, delivery of raw milk from the production holding is to be suspended or — in accordance with a specific authorisation of, or general instructions from, the competent authority — subjected to requirements concerning its treatment and use necessary to protect public health. This suspension or these requirements are to remain in place until the food business operator has proved that the raw milk again complies with the criteria. Besides these specific rules for the milk sector, **Regulation 854/2004 lays down general principles for inspection of food chain operators.** Article 4 - General principles for official controls 1. Member States shall ensure that food business operators offer all assistance needed to ensure that official controls carried out by the competent authority can be performed effectively. …	

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permits. Initial inspections and change of market inspections are required and shall be conducted by the Regulatory Agency in conjunction with the Certified Industry Inspector. When a producer changes market, the producer records for the preceding twenty-four (24) months shall be transferred with the producer, through the Regulatory Agency, and will continue to be a part of the producer's record. Industry personnel shall be certified every three (3) years by the Regulatory Agency. At least annually, the Certified Industry Inspector shall attend an educational seminar provided by the Regulatory Agency, or equivalent training acceptable to the Regulatory Agency. At least once in each six (6) month period, the Regulatory Agency shall inspect the records maintained by the Industry for the Certified Industry Inspection Program and conduct farm field work to assure the program meets the provisions of the Regulatory Agency's written plan and requirements of this *Ordinance* and related documents. Initial certification by the Regulatory Agency shall not be made during the course of an official inspection. Re-certification by the Regulatory Agency may be conducted during the course of an official inspection. **Purpose of Certification:** The purpose of certification is to have the applicant formally demonstrate their inspection ability to apply proper interpretations of this *Ordinance,* related	2. The competent authority shall carry out official controls to verify food business operators' compliance with the requirements of: (a) Regulation (EC) No 852/2004; (b) Regulation (EC) No 853/2004; and (c) Regulation (EC) No 1774/2002. 3. The official controls shall include: (a) audits of good hygiene practices and hazard analysis and critical control point (HACCP)-based procedures; … 4. Audits of good hygiene practices shall verify that food business operators apply procedures continuously and properly concerning at least: (a) checks on food-chain information; (b) the design and maintenance of premises and equipment; (c) pre-operational, operational and post-operational hygiene; (d) personal hygiene; (e) training in hygiene and in work procedures; (f) pest control; (g) water quality; (h) temperature control; and (i) controls on food entering and leaving the establishment and any accompanying	

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documents, and the Regulatory Agency's procedures. **Designation of Individuals to Be Certified:** Candidates shall submit requests for certification to the Regulatory Agency. The applicant for certification shall have had experience in the field of milk sanitation, and shall be an employee of a milk plant, a producer association, officially designated laboratory or shall be employed on a consulting basis. **Recording of Qualification Data:** Prior to conducting the certification procedure, background information shall be secured on the applicant. This shall include academic training, experience in milk sanitation and related fields, in-service courses attended, etc. This information is to be retained by the Regulatory Agency as part of the applicant's file, along with appropriate records of the applicant's performance during the certification examination. **Field Procedure:** Only one (1) applicant shall be certified at a time. The certification is to be conducted without prompting from the Regulatory Agency or comparison of inspection results in any way until the entire procedure is completed. Initial certification shall not be made during the course of an official inspection by the Regulatory Agency. At least twenty-five (25) randomly selected dairy farms and/or five (5) milk tank trucks shall be visited. After the necessary inspections have been completed, the Regulatory Agency shall compare their results with those of the candidate. The percentage agreement for each Item of sanitation	documentation. 5. Audits of HACCP-based procedures shall verify that food business operators apply such procedures continuously and properly... They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin: (a) comply with microbiological criteria laid down under Community legislation; (b) comply with Community legislation on residues, contaminants and prohibited substances; and (c) do not contain physical hazards, such as foreign bodies. 6. Verification of compliance with the requirements of Regulation (EC) No 853/2004 concerning the application of identification marks shall take place in all establishments approved in accordance with that Regulation, in addition to verification of compliance with other traceability requirements. .. When carrying out auditing tasks, the competent authority shall take special care: (a) to determine whether staff and staff activities in the establishment at all stages of the production process comply with the relevant requirements. To support the audit, the competent authority may carry out performance tests, in order to ascertain that staff performance meets specified parameters; (b) to verify the food business operator’s	

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shall be determined by dividing the number of agreements by the total number of dairy farms and/or milk tank trucks inspected. **Criteria for Certification:** In order to be certified, an industry inspector shall agree with the Regulatory Agency eighty percent (80%) of the time on individual Items of sanitation and shall further agree to comply with the administrative procedures established by the Regulatory Agency for the program of dairy farm and/or milk tank truck supervision. The Regulatory Agency should allow sufficient time to discuss the findings with the applicant. **Duration of Certification:** Certification of industry inspection personnel shall be for a period not exceeding three (3) years from the date of formal certification or re-certification, unless revoked. **Re-Certification:** The Regulatory Agency shall notify the certified industry inspector of the need for certification renewal at least sixty (60) days prior to its expiration. If re-certification is desired, the inspector will make appropriate arrangements for the renewal procedure. Re-certification can be made for the succeeding three (3) year period, by following the procedures outlined above. Provided, that re-certification may be conducted during the course of an official inspection by the Regulatory Agency. **Reports and Records:** Upon satisfactory completion of certification or re-certification, the certified industry inspector shall be issued a certificate. The milk plant(s) or officially designated laboratory(ies) employing the inspector shall be	relevant records; (c) to take samples for laboratory analysis whenever necessary; and (d) to document elements taken into account and the findings of the audit. 9. The nature and intensity of auditing tasks in respect of individual establishments shall depend upon the assessed risk. To this end, the competent authority shall regularly assess: (a) public and, where appropriate, animal health risks; (b) in the case of slaughterhouses, animal welfare aspects; (c) the type and throughput of the processes carried out; and (d) the food business operator's past record as regards compliance with food law. **Regulation 882/2004 specifies the actions and sanctions to be used in cases of non-compliance.** Article 54 Action in case of non-compliance 1. When the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance. 2. Such action shall include, where appropriate, the following measures: (a) the imposition of sanitation procedures or	

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laboratory(ies) employing the inspector shall be formally notified by letter of the certification. The letter shall outline the purpose of the certification and the conditions under which the certification may be retained. A copy of the notification letter, together with a copy of the qualification data above and a resume of the percentage agreement on individual items, shall be retained by the Regulatory Agency. **Revocation of Certification:** The certification of an industry inspector may be revoked by the Regulatory Agency upon a finding that the inspector is: 1. Not in agreement with the Regulatory Agency at least eighty percent (80%) of the time on Items of sanitation in a field examination; or 2. Not complying with the established administrative procedures of the Regulatory Agency for the program; or 3. Failing to carry out the provisions of this *Ordinance* in the course of the inspector's work. **INSPECTION/AUDIT REPORTS:** A copy of the inspection/audit report shall be filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used. Examples of field inspection/audit forms are identified in Appendix M.	any other action deemed necessary to ensure the safety of feed or food or compliance with feed or food law, animal health or animal welfare rules; (b) the restriction or prohibition of the placing on the market, import or export of feed, food or animals; (c) monitoring and, if necessary, ordering the recall, withdrawal and/or destruction of feed or food; (d) the authorisation to use feed or food for purposes other than those for which they were originally intended; (e) the suspension of operation or closure of all or part of the business concerned for an appropriate period of time; (f) the suspension or withdrawal of the establishment's approval; (h) any other measure the competent authority deems appropriate. 3. The competent authority shall provide the operator concerned, or a representative, with: (a) written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision; and (b) information on rights of appeal against such decisions and on the applicable procedure and time limits. Article 55 - Sanctions Member States shall lay down the rules on sanctions applicable to infringements of feed and food law … and shall take all measures necessary to ensure that	

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	they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.	

6 Details of Examination

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It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank prior to transferring milk from a farm bulk tank, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency. 1. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section. 2. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing, shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization or aseptic processing. 3. During any consecutive six (6) months, at least four (4) samples of heat-treated milk products, from milk plants offering such products for sale	As outlined above, Regulation 852/2004 requires all milk processing establishments to implement HACCP-based control systems (Article 5 - Hazard analysis and critical control points). Dairy farms must keep records on the feed used, veterinary treatments and drugs applied, diseases, and any relevant reports on checks carried out (Annex I to Regulation 852/2004). Regulation 853/2004 Annex II, Section IX provides minimum standards: III. CRITERIA FOR RAW MILK: 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. Food business operators must initiate procedures to ensure that raw milk	As already noted in the previous Section, the EC-legislation largely avoids the fixation of exact frequencies of sampling but prescribes the objective that 'a representative number of samples' must be examined. There is one exception: Sampling frequency for somatic cell counts and plate counts of raw milk is defined under EU rules and is in this particular case exceeds the requirement of the US ordinance. Analytical methods and other provisions to ensure consistent quality of sampling and laboratory analyses are very similar in both pieces of legislation. Also the consequences of non-compliance are very similar. The European food law does not foresee the fortification of milk with Vitamins A or D and, therefore, does not make specific provisions for such a fortification.

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from milk plants offering such products for sale, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. 4. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, flavored milk, flavored reduced fat or lowfat milk, flavored nonfat (skim) milk, each fat level of reduced fat or lowfat milk and each milk product defined in this *Ordinance*, (including aseptically processed milk and milk products for drug residue tests) shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. **NOTE:** If the production of any Grade "A" condensed or dry milk product as defined in this *Ordinance* is not on a yearly basis, at least 5 samples shall be taken within a continuous production period. Samples of milk and milk products shall be taken while in the possession of the producer, milk plant or distributor at any time prior to delivery to the store or consumer. Samples of milk and milk products from dairy retail stores, food service establishments, grocery stores and other places where milk and milk products are sold shall be examined periodically as determined by the Regulatory Agency and the results of such examination shall be used to determine compliance with Sections 2, 4 and 10. Proprietors of such	meets the following criteria: (i) for raw cows' milk: Plate ct. 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. (ii) for raw milk from other species: Plate count (per ml) < 1.500.000 * * Rolling geometric average over a two-month period, with at least two samples per month. 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 (per ml) < 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, exceeds the levels authorised; or (b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.	

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establishments shall furnish the Regulatory Agency, upon request, with the names of all distributors from whom milk or milk products are obtained. Required bacterial counts somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization. In addition, drug tests on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months. Required bacterial counts, drug tests, except those products for which there are not any approved drug test kits available, coliform determinations, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized milk and milk products defined in this *Ordinance*. Required drug residue tests shall be performed on aseptically processed milk and milk products. Whenever two (2) of the last four (4) consecutive bacterial counts (except those for aseptically processed milk and milk products), somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products as defined in this *Ordinance*, the Regulatory Agency shall send a written notice thereof to the person concerned. This notice shall be in effect as long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. Immediate suspension of permit, in accordance with Section 3, and/or court action shall be instituted whenever the standard is violated by three (3) of the last five (5)	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. Requirements for dairy products: 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. When milk fails to meet these criteria the food business operator must inform the competent authority and take measures to correct the situation. Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products lists in particular antibiotics, pesticide residues, anthelmintics and other veterinary drugs, which must be monitored. A sampling frequency is not specified but a residue monitoring plan must be submitted and approved at EU level. Commission Decision 91/180/EEC prescribes specific methods for the determination of somatic cell count, plate count, phosphatase and peroxidase activity, and for antimicrobial residue testing.	

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bacterial counts (except those for aseptically processed milk and milk products), somatic cell counts, coliform determinations or cooling temperatures. Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or milk product involved shall not be offered for sale. Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no milk or milk products as defined in this *Ordinance* shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues. Whenever a drug residue test is confirmed positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N. Whenever a container or containers of aseptically processed milk or milk product is found to be non-sterile, due to under-processing, the Regulatory Agency shall consider this to be an imminent hazard to public health and shall suspend the permit of the milk plant for the sale of aseptically processed milk and milk products. No aseptically processed milk and milk product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All products from the lot that were found to	As outlined in the previous Section, Regulation 854//2004 provides in its Annex IV further rules on inspection: Chapter I: Control of Milk Production Holdings … 3. Milk production holdings are to undergo official controls to verify that hygiene requirements are being complied with. These official controls may involve inspections and/or the monitoring of controls that professional organizations carry out. If it is shown that the hygiene is inadequate, the competent authority is to verify that appropriate steps are taken to correct the situation. Chapter II: Control of Raw Milk Upon Collection 1. The competent authority is to monitor the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III, to Regulation (EC) No 853/2004. 2. If the food business operator has not corrected the situation within three months of first notifying the competent authority of non-compliance with the criteria with regard to plate count and somatic cell count, delivery of raw milk from the production holding is to be suspended... This suspension or these requirements are to remain in place until the food business operator has proved that the raw milk again complies with the criteria. Regulation 882/2004 on Official Controls provides	

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contain one (1) or more non-sterile units shall be recalled and disposed of as directed by the Regulatory Agency. Samples shall be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers, and required laboratory examinations shall be in substantial compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* (SMEDP) of the American Public Health Association, and the most current edition of *Official Methods of Analysis of AOAC INTERNATIONAL* (OMA). Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the *EML*. Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with FDA's *Bacteriological Analytical Manual* (BAM). Each milk plant regulated under the NCIMS HACCP Program shall adequately document its response to each regulatory sample test result that exceeds any maximum level specified in Section 7 of this *Ordinance*. The Regulatory Agency will monitor and verify that appropriate action(s) was taken by the milk plant. Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Regulatory Agency requires. When the Commissioner of the FDA determines that a potential problem exists with animal drug residues or other contaminants in the milk supply, samples shall be analyzed for the contaminant by a method(s)	several further, relevant elements: Article 8 - Control and verification procedures 1. Competent authorities shall carry out official controls in accordance with documented procedures. … 2. Member States shall ensure that they have legal procedures in place in order to ensure that staff of the competent authorities have access to premises of and documentation kept by feed and food business operators so as to be able to accomplish their tasks properly. 3. Competent authorities shall have procedures in place: a. to verify the effectiveness of official controls that they carry out; and b. to ensure that corrective action is taken when needed and that the documentation referred to in paragraph 1 is updated as appropriate Article 9 - Reports 1. The competent authority shall draw up reports on the official controls that it has carried out. 2. These reports shall include a description of the purpose of the official controls, the control methods applied, the results of the official controls and, where appropriate, action that the business operator concerned is to take. 3. The competent authority shall provide the business operator concerned with a copy of the report. Article 10 - Control activities, methods, techniques 1. Tasks related to official controls shall, in general, be carried out using appropriate control	

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determined by FDA to be effective in determining compliance with actionable levels or established tolerances. This testing will continue until such time that the Commissioner of the FDA is reasonably assured that the problem has been corrected. The determination of a problem is to be based upon: - Sample survey results; - USDA tissue residue data from cull and veal dairy animals; - Animal drug disappearance and sales data; - State feed back; and - Other relevant information. Assays of milk and milk products as defined in this *Ordinance*, to which vitamin (s) A and/or D have been added, shall be made at least annually in a laboratory, which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies, which gives statistically equivalent results to the FDA methods. Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the *EML* manual. In addition, all facilities fortifying milk or milk products with vitamins must keep volume control records. These volume control records must cross reference the form and amount of vitamin D, vitamin A and/or vitamins A and D used with the amount of products produced and indicate a percent of expected use, plus or minus.	methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis. 2. Official controls on feed and food shall include, inter alia, the following activities: c. examination of any control systems that feed and food business operators have put in place; d. inspection of: (i) primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food; (ii) raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food; (iii) semi-finished products; (iv) materials and articles intended to come into contact with food; (v) cleaning and maintenance products and processes, and pesticides; (vi) labelling, presentation and advertising; e. checks on the hygiene conditions in feed and food businesses; f. assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with Community legislation; g. examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;	

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ENFORCEMENT PROCEDURES: All violations of bacteria, coliform, confirmed somatic cell counts and cooling temperature standards should be followed promptly by inspection to determine and correct the cause. Aseptically processed milk and milk products packaged in hermetically sealed containers are exempt from the refrigerated storage requirements of this *Ordinance*. Therefore, whenever a breakdown in the processing or packaging of these products occurs an imminent hazard to public health exists. Prompt action is needed by the Regulatory Agency. Milk plants aseptically processing milk and milk products in hermetically sealed containers should be encouraged to perform bacterial and other quality tests on each lot of aseptically processed milk and milk product produced in order to ascertain that these products have been properly processed and have not been rendered non-sterile after aseptic processing and packaging. The Regulatory Agency may utilize industry records, of each lot of aseptically processed milk and milk products, to determine when lots can be released for sale after a violation of the bacterial standards has existed. **LABORATORY TECHNIQUES:** Procedures for the collection, including the use of approved in-line samplers, and holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the FDA 2400 series forms, *SMEDP* and *OMA*. The procedures shall be those	law; h. interviews with feed and food business operators and with their staff; i. the reading of values recorded by feed or food business measuring instruments; j. controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators; k. any other activity required to ensure that the objectives of this Regulation are met. Article 12 - Official laboratories 1. The competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls. 2. However, competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards: (a) EN ISO/IEC 17025 (b) EN 45002 (c) EN 45003 taking into account criteria for different testing methods laid down in Community feed and food law. 3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests. 4. The competent authority may cancel the designation referred to in paragraph 1 when the conditions referred to in paragraph 2 are no longer fulfilled. As described in the previous Section, Articles 54 and 55 of Regulation 882/2004 define regulatory action	

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specified therein for: Standard plate count at 32°C (agar or Petrifilm method). Alternate methods, including the Plate Loop Count, and the BactoScan FC for viable counts for raw milk, and the Petrifilm method for pasteurized milk and milk products at 32°C. Coliform test with solid media or Petrifilm method at 32°C for all milk and milk products, and the Petrifilm High Sensitivity Coliform Count method for all milk and milk products, except unflavored whole, reduced or low fat and nonfat (skim) milk. A viable bacterial count of nonfat dry milk and dry whey shall be made in accordance with the procedures in *SMEDP* for the Standard Plate Count of Dry Milk, except agar plates shall be incubated for 72 hours. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA for detecting drug residues in raw milk, or pasteurized milk, or that particular type of pasteurized milk product at current safe or tolerance levels, shall be used for each drug of concern, except those products for which there are not any approved drug test kits available. Regulatory action shall be taken on all confirmed positive results. A result shall be considered positive if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV of Appendix N. Screening and Confirmatory Methods for the	and sanctions in the case of non-compliance. "The competent authority shall take account of the nature of the noncompliance." The Commission is empowered to ensure proper implementation of these provisions: Article 56 - Safeguard measures 2. Measures shall be taken under the procedures provided for in Article 53 of Regulation (EC) No 178/2002 if: a. the Commission has evidence of a serious failure in a Member State's control systems; and b. such failure may constitute a possible and widespread risk for human health, animal health or animal welfare. 3. Such measures shall be adopted only after: a. Community controls have shown and reported non-compliance with Community legislation and b. the Member State concerned has failed to correct the situation upon request and within the time limit set by the Commission.	

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Detection of Abnormal Milk: The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer. When a warning letter has been sent, because of excessively high somatic cell counts, an official inspection of the dairy should be made by regulatory personnel or certified industry personnel. This inspection should be made during milking time. Milk (Non-Goat):Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting. Goat Milk: In addition to the above mentioned tests, the Wisconsin Mastitis Test or California Mastitis Test may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,000,000/mL. Laboratories using the Wisconsin Mastitis Test or California Mastitis Test for goat milk shall confirm samples of herd milk that exceeds 18mm, or a value of one (1), respectively. Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting. Pyronine Y-Methyl green stain or "New York modification" shall be used in the confirmatory test for Direct Microscopic Somatic Cell Counts in goat milk.		

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American Public Health Association (APHA), Association of Official Analytical Chemists (AOAC), or Electronic Phosphatase Tests: The phosphatase test is an index of the efficiency of the pasteurization process. In the event the laboratory phosphatase test is positive, the cause shall be determined immediately. Where the cause is improper pasteurization, it shall be corrected. When a laboratory phosphatase test is positive, or if any doubt should arise as to the compliance of the equipment, standards or methods outlined in Section 7, Item 16p, the Regulatory Agency should immediately conduct field phosphatase test at the milk plant. Vitamin testing shall be performed using test methods acceptable to FDA or other official methodologies, which give statistically equivalent results to the FDA methods. All standards used in the development and use of drug residue detection methods designed for *Grade "A" PMO* monitoring programs will be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method must define the standard to be used. Procedural or reagent changes for official tests must be submitted to FDA for acceptance prior to being used by certified NCIMS milk laboratories. **SAMPLING PROCEDURES:** *SMEDP* contains guidance for sampling of milk and milk products. (Refer to Appendix G. for a reference to drug residues in milk and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream. Refer to		

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Appendix B. for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.) When samples of raw milk for pasteurization are taken at a milk plant prior to pasteurization, they shall be drawn following adequate agitation from randomly selected storage tanks. All counts and temperatures should be recorded on a milk-ledger form as soon as reported by the laboratory. A computer or other information retrieval system may be used. **NOTE:** Milk from animals not currently in the *Grade "A" PMO* may be labeled as Grade "A" and IMS listed upon FDA's acceptance of validated *Grade "A" PMO*, Section 6 and Appendix N. test methods for the animal to be added.		

7 Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
This Section of the Milk Ordinance gives detailed provisions for the construction, design and operation of all operations in the milk production chain. Standards For Grade "A" Raw Milk 1. Abnormal Milk Lactating animals which show evidence of the secretion of abnormal milk in one or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. Lactating animals treated with, or lactating animals which have consumed chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Regulatory Agency, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Regulatory Agency may direct.	**Regulation 853/2004 provides in Annex II Section IX Chapter I for the primary production of raw milk:** 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.	In general, all aspects addressed by the US Milk Ordinance are addressed also in the EU Hygiene Regulations, albeit in broader, more general terms. Hygiene hazards identified in both pieces of legislation, which must be addressed by operators and which must be subject to inspection are largely identical.

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2. Milking Barn, Stable or Parlor - Construction 3. Milking Barn, Stable or Parlor - Cleanliness 4. Cowyard 5. Milkhouse - Construction and Facilities 6. Milkhouse - Cleanliness 7. Toilet 8. Water Supply 9. Utensils and Equipment - Construction 10. Utensils and Equipment - Cleaning 11. Utensils and Equipment - Sanitization 12. Utensils and Equipment - Storage 13. Milking - Flanks, Udders and Teats 14. Protection From Contamination 15. Drug and Chemical Control 16. Personnel - Handwashing Facilities 17. Personnel - Cleanliness 18. Raw Milk Cooling 19. Insect and Rodent Control Standards For Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products 1. Floors - Construction 2. Walls and Ceilings - Construction 3. Doors and Windows 4. Lighting and Ventilation 5. Separate Rooms 6. Toilet-Sewage Disposal Facilities 7. Water Supply 8. Handwashing Facilities 9. Milk Plant Cleanliness 10. Sanitary Piping 11. Construction and Repair of Containers and	The same Chapter provides specific requirements for 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. 2. Premises for the storage of milk must be protected against vermin, have adequate separation from premises where animals are housed and 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	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
Equipment 12. Cleaning and Sanitizing of Containers and Equipment 13. Storage of Cleaned Containers and Equipment 14. Storage of Single-Service Containers, Utensils and Materials 15. Protection From Contamination 16. Pasteurization 17. Cooling of Milk 18. Bottling and Packaging 19. Capping 20. Personnel - Cleanliness 21. Vehicles 22. Surroundings	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 after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC concerning the placing of biocidal products on the market. 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	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
	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. **Further, general hygiene requirements concerning construction and design of rooms, equipment, transport, personal hygiene and other provisions are laid down in Annex II to Regulation 852/2004** Chapter I - General requirements Chapter II - Specific requirements in rooms where foodstuffs are prepared, treated or processed Chapter III - Requirements for movable and/or temporary premises (Chapter IV - Transport Chapter V –Equipment Chapter VI - Food waste Chapter VII – Water supply Chapter VIII – Personal hygiene Chapter IX - Provisions applicable to foodstuffs	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
	Chapter X - Wrapping and packaging Chapter XI - Heat treatment Chapter XII - Training **Specific minimum requirements for pasteurization or ultra-high temperature treatment of milk products are also made in Appendix II Section IX to Regulation 853/2004:** **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 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:	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
	(a) Pasteurisation is achieved by a treatment involving: (i) a high temperature for a short time (at least 72 °C for 15 seconds); (ii) a low temperature for a long time (at least 63 °C for 30 minutes); or (iii) 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. (b) Ultra high temperature (UHT) treatment is achieved by a treatment: (i) 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 micro-organisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature; and (ii) sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30 °C in closed containers or for 7 days at 55 °C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied. 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.	

8 Animal Health

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
1. All milk for pasteurization shall be from herds in Areas which have a Modified Accredited Advanced Tuberculosis status or greater as determined by the USDA. Provided, that in an Area which fails to maintain such status, any herd shall have been accredited by said Department as tuberculosis free, or shall have passed an annual tuberculosis test, or the Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that it is approved by FDA, USDA and the Regulatory Agency. 2. All milk for pasteurization shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions: a. Located in a Certified Brucellosis-Free Area as defined by USDA and enrolled in the testing program for such areas; or b. Meet USDA requirements for an individually certified herd; or c. Participating in a milk ring testing program at least two (2) times per year at approximately one hundred eighty (180) day intervals and all herds with positive milk ring results shall have the entire herd blood tested within thirty (30) days from the date of the laboratory ring tests; or d. Have an individual blood agglutination test annually with an allowable maximum grace	**Regulation 853/2004 provides in Annex II Section IX Chapter I for the primary production of raw milk:** 1. (see previous Section, general health provisions) 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, is free of brucellosis; (ii) sheep or goats belonging to a holding free of brucellosis within the meaning of Directive 91/68/EEC;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	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
annually with an allowable maximum grace period not exceeding two (2) months. 3. Goat, sheep, water buffalo, or any other hoofed mammal milk for pasteurization, ultra-pasteurization or aseptic processing, defined under this *Ordinance*, shall be from a herd or flock that: a. Has passed an annual whole herd or flock brucellosis test as recommended by the State Veterinarian or USDA Area Veterinarian in Charge (AVIC); or b. Has passed an initial whole herd brucellosis test, followed only by testing replacement animals or any animals entering the milking group or sold as dairy animals; or c. Has passed an annual random blood-testing program sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one (1) or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found; or d. Has passed a USDA approved bulk milk test, at USDA recommended frequency, with an implementation date based on availability of the test. 4. For diseases other than brucellosis and tuberculosis, the Regulatory Agency shall require such physical, chemical or bacteriological tests, as it deems necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed and accredited[14] veterinarian or an accredited veterinarian in the employ of an official	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	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
veterinarian in the employ of an official Agency. Any diseased animal disclosed by such test(s) shall be disposed of as the Regulatory Agency directs. 5. Records supporting the tests required in this Section shall be available to the Regulatory Agency and be validated with the signature of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official Agency. **ADMINISTRATIVE PROCEDURES** **BOVINE TUBERCULOSIS:** All tuberculin tests and retests shall be made, and any reactors disposed of, in accordance with the current edition of *Uniform Methods and Rules; Bovine Tuberculosis Eradication, Uniform Methods and Rules for Establishment and Maintenance of Tuberculosis-Free Accredited Herds of Cattle, Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine*, as published by USDA. For tuberculosis test purposes, the herd is defined as all adult cattle twenty-four (24) months of age and over, including any commingled beef animals. Dairy cattle less than two (2) years of age and already milking shall be included in the herd test. A letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation, or a certificate identifying the animals tested, the date of injection, the date of reading of the test and the results of the test signed by a USDA accredited veterinarian, shall be evidence of compliance with the above requirements and shall be	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. **Directive 64/432/EEC provides for bovines (Annex A, Part I):** 1. A bovine herd is **officially tuberculosis-free** if: a. all the animals are free from clinical signs of tuberculosis; b. all the bovine animals over six weeks old have reacted negatively to at least two official intradermal tuberculin tests carried out in accordance with Annex B, the first six months after the elimination of any infection from the herd and the second six months later or, where the herd has been assembled solely from animals that originate in officially tuberculosis-free herds, the first test shall be carried out at least 60 days after assembly and the second shall not be required; c. following the completion of the first test referred to in (b), no bovine animal over six weeks old has been introduced into the herd unless it has reacted negatively to an intradermal tuberculin test performed and assessed according to Annex B and carried out either in the 30 days prior to, or the 30 days after the date of its introduction into the herd; in the latter case the animal(s)	

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filed with the Regulatory Agency. (Refer to Appendix A.) **BOVINE BRUCELLOSIS:** All brucellosis tests, retests, disposal of reactors, vaccination of calves and certification of herds and areas shall be in accordance with the current edition of *Brucellosis Eradication, Recommended Uniform Methods and Rules*, as published by USDA. All reactors disclosed on blood agglutination tests shall be separated immediately from the milking herd and the milk of these reactors shall not be used for human consumption. A certificate identifying each animal, signed by the veterinarian and the director of the laboratory making the test, shall be filed as directed by the Regulatory Agency. Provided, that in the event the herd is subject to the milk ring test, the record shall be required to show only the date and results of such test. Within thirty (30) days following the expiration of an official milk ring testing program, or in the	the herd; in the latter case the animal(s) must be isolated physically from the other animals of the herd in a way to avoid any direct or indirect contact with the other animals until proven negative. However, the competent authority may not require this test to be carried out for movements of animals on its own territory if the animal is from an officially tuberculosis-free herd, except in a Member State where, on 1 January 1998 and until the status of officially tuberculosis-free region is obtained, the competent authority required such tests to be carried out for animals moving between herds participating in a network system as referred to in Article 14. 2. A bovine herd will retain **officially tuberculosis-free status** if: a. the conditions detailed in 1(a) and (c) continue to apply; b. all animals entering the holding come from herds of officially tuberculosis-free status; all animals on the holding, with the exception of calves under six weeks old which were born in the holding, are subjected to routine tuberculin testing in accordance with Annex B at yearly intervals. … 1. A bovine herd is officially brucellosis-free if: a. it contains no bovine animals which have been vaccinated against brucellosis, except females which have been vaccinated at least three years previously; b. all the bovine animals have been free from clinical signs of brucellosis for at least six	

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case of a herd subject to annual blood tests, thirteen (13) months following the last annual blood tests, the Regulatory Agency shall notify the herd owner or operator of the necessity to comply with the brucellosis requirements. The failure of the herd owner or operator to comply with the brucellosis requirements within thirty (30) days of written notice shall result in immediate suspension of the permit.	months; c. all the bovine animals over 12 months old have been subjected to one of the following test regimes with negative results in accordance with Annex C: (i) two serological tests specified in paragraph 10 at an interval of more than three months and less than 12 months; (ii) three tests on milk samples at three-monthly intervals followed at least six weeks later by a serological test specified in paragraph 10; d. any bovine animal entering the herd comes from a herd of officially brucellosis-free status and, in the case of bovine animals over 12 months old, has shown a brucella titre of less than 30 IU of agglutination per ml when given a serum agglutination test in accordance with Annex C or has reacted negatively to any other test approved in accordance with the procedure at Article 17 during the 30 days prior to or the 30 days after the date of its introduction into the herd: in the latter case, the animal(s) must be isolated physically from the other animals of the herd in such a way as to avoid direct or indirect contact with the other animals until proven negative. 2. A bovine herd will retain officially brucellosis-free status if: a. one of the following test regimes is carried out annually with negative results in accordance with Annex C: (i) three milk ring tests carried out at intervals of at least three months;	

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	(ii) three milk ELISAs carried out at intervals of at least three months; (iii) two milk ring tests carried out at an interval of at least three months followed at least six weeks later by a serological test referred to in paragraph 10; (iv) two milk ELISAs carried out at an interval of at least three months followed at least six weeks later by a serological test referred to in paragraph 10; (v) two serological tests carried out at an interval of at least three months and not more than 12 months. **Regulation 854/2004, Annex IV - Raw Milk And Dairy Products; Chapter I - Control Of Milk Production Holdings:** 1. Animals on milk production holdings must be subject to official controls to verify that the health requirements for raw milk production, and in particular the health status of the animals and the use of veterinary medicinal products, are being complied with. These controls may take place at the occasion of veterinary checks carried out pursuant to Community provisions on animal or public health or animal welfare and may be carried out by an approved veterinarian. 2. If there are grounds for suspecting that the animal health requirements are not being complied with, the general health status of the animals is to be	

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	checked. 3. Milk production holdings are to undergo official controls to verify that hygiene requirements are being complied with. These official controls may involve inspections and/or the monitoring of controls that professional organisations carry out. If it is shown that the hygiene is inadequate, the competent authority is to verify that appropriate steps are taken to correct the situation. **Chapter II: Control of raw milk upon collection** 1. The competent authority is to monitor the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III, to Regulation (EC) No 853/2004. 2. If the food business operator has not corrected the situation within three months of first notifying the competent authority of non-compliance with the criteria with regard to plate count and somatic cell count, delivery of raw milk from the production holding is to be suspended or - in accordance with a specific authorisation of, or general instructions from, the competent authority - subjected to requirements concerning its treatment and use necessary to protect public health. This suspension or these requirements are	

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	to remain in place until the food business operator has proved that the raw milk again complies with the criteria.	

9 Milk which may be sold

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
From and after twelve (12) months from the date on which this *Ordinance* is adopted, only Grade "A" pasteurized, ultra-pasteurized, or aseptically processed milk and milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. Provided, only Grade "A" milk and milk products shall be sold to milk plants for use in the commercial preparation of Grade "A' milk and milk products. Provided further, that in an emergency, the sale of pasteurized milk and milk products, which have not been graded, or the grade of which is unknown, may be authorized by the Regulatory Agency, in which case, such milk and milk products shall be labelled "ungraded".	**Regulation 852/2004 provides:** ***Article 3*** ***General obligation*** Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation. **Regulation 853/2004 contains further obligations, which are relevant for milk and milk products:** ***Article 4*** ***Registration and approval of establishments*** 1. 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: a. 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 b. that the competent authority has registered or, where required, approved.	This is largely a legalistic formality: Both legislations ensure that milk (-products) placed on the market must comply with all relevant legal requirements.

10 Transferring, Delivery Containers, and Cooling

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
Except as permitted in this Section, no milk producer, bulk milk hauler/sampler or distributor shall transfer milk or milk products from one (1) container or milk tank truck to another on the street, in any vehicle, store or in any place except a milk plant, receiving station, transfer station or milkhouse especially used for that purpose. The dipping or ladling of milk or fluid milk products is prohibited. It shall be unlawful to sell or offer for sale any pasteurized milk or milk products that have not been maintained at the temperature set forth in Section 7 of this *Ordinance*. If containers of pasteurized milk or milk products are stored in ice, the storage container shall be properly drained. **ADMINISTRATIVE PROCEDURES** **TRANSFERRING:** The dipping or ladling of milk and fluid milk products is expressly prohibited, except for immediate cooking purposes. Milk and milk product containers, which have been filled and sealed at a milk plant, shall be used for the delivery of milk or milk products. Caps, closures or labels shall not be removed or replaced during transportation. **BULK DISPENSERS:** Bulk dispensers, approved by the Regulatory Agency, shall satisfy the following sanitary design, construction and operation requirements:	**Annex II to Regulation 852/2004 makes similar provisions:** ***CHAPTER IV - Transport*** 1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection. 2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination. 3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products. 4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
1. All dispensers shall comply with the applicable requirements of Section 7 of this Ordinance. 2. Product-contact surfaces shall be inaccessible to manual contact, droplet infection, dust or insects, but the delivery orifice may be exempted from this requirement. 3. All parts of the dispensing device with which milk or milk products come into contact, including any measuring device, shall be thoroughly cleaned and sanitized at the milk plant. Provided, that dispensing valves, which are applied to the dispenser subsequent to its delivery to the retail vendor may be cleaned and sanitized at such establishments. 4. The dispensing container shall be filled at the milk plant and shall be sealed so that it is impossible to withdraw any part of its contents, or to introduce any substance without breaking the seal(s). 5. The milk or milk products shall be thoroughly and automatically mixed with each dispensing operation, except for milk or milk products that remain homogeneous. 6. All cans shall be thoroughly cleaned and sanitized. Milk and milk products shall be kept at or below 7°C (45°F) at all times. The dispenser tube shall be integral with the dispensing container, shall be protected and shall be under adequate refrigeration during transportation and storage.	one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked 'for foodstuffs only'. 5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination. 6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination. 7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored. ***CHAPTER V - Equipment requirements*** 1. All articles, fittings and equipment with which food comes into contact are to: a. be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination; b. be so constructed, be of such	

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
	materials and be kept in such good order, repair and condition as to minimise any risk of contamination; c. with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected; and d. be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area. 2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives. 3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice. **Regulation 853/2004, Annex III, Section IX: Raw Milk And Dairy Products; Chapter I: Raw Milk - Primary Production:** II. Hygiene on milk production holdings B. Hygiene during milking, collection and transport 1. …	

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	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 *(i.e. cell count and plate count, see Chapter 6 above)* 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.	

11 Milk and Milk Products From Points Beyond the Limits of Routine Inspection

Pasteurized Milk Ordinance	Harmonized EU Legislation	Summary and conclusion
Milk and milk products, from points beyond the limits of routine inspection shall be sold in its jurisdiction provided they are produced and pasteurized, ultra-pasteurized, aseptically processed, concentrated (condensed) or dried under regulations which are substantially equivalent to this *Ordinance* and have been awarded acceptable Milk Sanitation Compliance and Enforcement Ratings or have been awarded a satisfactory HACCP listing, under the NCIMS HACCP Program as specified in Appendix K. of this *Ordinance*. **ADMINISTRATIVE PROCEDURES** **The Regulatory Agency should accept, without their actual physical inspection, supplies of milk and milk products from an area or an individual shipper not under their routine inspection.** Provided, that: 1. Milk and milk products upon arrival shall comply with bacteriological, physical, chemical and temperature standards of Section 7. Provided, that direct shipped producer milk that is under the supervision of more than one (1) Regulatory Agency may be exempt from the bacteriological requirement for commingled samples. However, the receiving Regulatory Agency shall have the right to use the individual producer samples to determine compliance with the bacteriological	**The General Food Law laid down in Regulation 178/2002 provides in Article 11 Food and feed imported into the Community** Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein. **Regulation 852/2004 Article 10: Imports** As regards the hygiene of imported food, the relevant requirements of food law referred to in Article 11 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation. *[**Article 3 General obligation:*** *Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.* ***Article 4 General and specific hygiene requirements:*** *Food business operators … shall comply with the general hygiene provisions …and any specific requirements provided for in Regulation (EC) No 853/2004.*	These provisions constitute the legal basis for accepting imports from sources outside the jurisdiction of the respective authorities. Both, the US milk ordinance and the EU food law accept imports under the general condition that that the milk and milk products are regulated under equivalent safety standards in the exporting country. The US rules require a rating by a Milk Sanitation Rating Officer (SRO) certified by FDA. EU rules require a listing of the exporting country, which requires a thorough evaluation of the entire milk sector. Once listed, the Competent Authorities of the exporting country may inspect and propose establishments for export ('pre-listing'), which are then approved by the Commission.

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compliance with the bacteriological standards. 2. After receipt, pasteurized, ultra-pasteurized, aseptically processed, concentrated (condensed) or dried milk and milk products shall comply with Sections 2, 4 and 10. **NOTE:** Raw and pasteurized milk and milk products beyond the limits of routine inspection shall be sampled as the Regulatory Agency requires. **3. The milk or milk products are produced and processed under regulations substantially equivalent to those of this Ordinance.** 4. The supplies are under routine official supervision; 5. The supplies have been awarded, by a Milk Sanitation Rating Officer (SRO), certified by FDA, Milk Sanitation Compliance and Enforcement Ratings equal to that of the local supply or equal to ninety percent (90%) or higher; and 6. All ratings are made on the basis of procedures outlined in the *Methods of Making Sanitation Ratings of Milk Supplies* (MMSR). **NOTE:** Names of interstate milk shippers and their ratings, as reported by State Rating Agencies, are contained in the *IMS List*	***Article 5 Hazard analysis and critical control points:*** *Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.* ***Article 6 Official controls, registration and approval:*** *… every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment]* **Regulation 853/2004 Article 6 : Products of animal origin from outside the Community** 1. Food business operators importing products of animal origin from third countries shall ensure that importation takes place only if: a. the third country of dispatch appears on a list, drawn up in accordance with Article 11 of Regulation (EC) No 854/2004, of third countries from which imports of that product are permitted; b. the establishment from which that product was dispatched, and in which it was obtained or prepared, appears on a list, drawn up in accordance with Article 12	

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Agencies, are contained in the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (IMS List), issued semi-annually by FDA. Copies of this list may be obtained from the State Milk Rating/Regulatory Agency or from the Food and Drug Administration, HFS-626, 5100 Paint Branch Parkway, College Park, MD 20740-3835. 7. The supplies have been awarded, by a SRO, certified by FDA, a satisfactory listing under the NCIMS HACCP Program as specified in Appendix K. of this *Ordinance*.	of Regulation (EC) No 854/2004, of establishments from which imports of that product are permitted, when applicable, in the case of fresh meat, minced meat, meat preparations, meat products and MSM, the product was manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with Article 12 of Regulation (EC) No 854/2004 or in approved Community establishments, and c. the product satisfies: (i) the requirements of this Regulation, including the requirements of Article 5 on health and identification marking; (ii) the requirements of Regulation (EC) No 852/2004; and (iii) any import conditions laid down in accordance with Community legislation governing import controls for products of animal origin, and d. the requirements concerning certificates and documents are satisfied, when applicable.	

12 Plans for Construction and Re-construction

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Properly prepared plans for all milk houses, milking barns, stables and parlors, milk tank truck cleaning facilities, milk plants, receiving stations and transfer stations regulated under this *Ordinance,* which are hereafter constructed, reconstructed or extensively altered shall be submitted to the Regulatory Agency for written approval before work is begun.	No such provision exists in EU law. Primary production of milk must comply with the general rules for hygiene and record keeping in production, handling and transport (Regulation 852/2004, Annex I). Regulation 853/2004, Annex III Section IX, chapter I provides: 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. 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	The EU law does not foresee an approval of constructions before their realisation. However, establishments not in compliance with legal provisions cannot be authorised and must not place milk or milk products on the market.

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	maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.	

13 Personnel Health

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No persons affected with any disease capable of being transmitted to others through the contamination of food shall work at a milk plant in any capacity which brings them into direct contact with pasteurized milk or milk products or which brings them into direct contact with associated pasteurized or aseptically processed milk or milk product-contact surfaces. In the case of milk plants, receiving stations, or transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, the HACCP System shall address the public health concerns described in this Section in a manner that provides protection equivalent to the requirements in this Section. **ADMINISTRATIVE PROCEDURES** Milk plant operators who have received reports, under this Section, from employees who have handled pasteurized milk or milk products or associated milk or milk product-contact surfaces shall immediately report these facts to the appropriate Milk Regulatory Agency. Milk plant employees, or applicants to whom a conditional offer of employment has been made, shall be instructed by the milk plant that the employee or applicant or applicants to whom a conditional offer of employment has been made is responsible to report to the milk plant management,	**Regulation 852/2004, Annex II Chapter VIII - Personal hygiene** 1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing. 2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.	The objectives laid down in EU legislation are identical to those of Sections 13 and 14 of the US Milk Ordinance. The detailed implementation of these objectives is not fixated in the EU hygiene provisions in the same amount of detail.

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in a manner that allows the milk plant to prevent the likelihood of the transmission of diseases that are transmissible through foods, if the employee or applicant to whom a conditional offer of employment has been made: 1. Is diagnosed with an illness due to Hepatitis A virus, Salmonella typhi, Shigella species, Norwalk and Norwalk-like Viruses, Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli 0157:H7, enterohemorrhagic Escherichia coli, enterotoxigenic Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia, Non-typhoidal Salmonella, Rotovirus, Taenia solium, Yersinia enterocolitica, Vibrio cholerae O1 or other infectious or communicable disease that has been declared by the Secretary of Health and Human Services (HHS) to be transmissible to others through the handling of food, or has been clearly shown to be so based upon verifiable epidemiological data; or 2. Is exposed to, or suspected of causing, a confirmed foodborne disease outbreak of one (1) of the diseases specified in Item 1 above, including an outbreak at an event such as a family meal, church supper or ethnic festival because the employee or applicant to whom a conditional offer of employment has been made: a. Prepared food implicated in the outbreak; or b. Consumed food implicated in the outbreak; or		

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c. Consumed food at the event prepared by a person who is infected or ill. 3. Lives in the same household as a person who attends or works in a day care center or school, similar institution experiencing a confirmed outbreak of one (1) of the diseases specified in Item 1 above. Similarly, milk plant employees shall be instructed by the milk plant management to report to the milk plant management if the employee, or applicant to whom a conditional offer of employment has been made. 4. Has a symptom associated with acute gastrointestinal illness such as: Abdominal cramps or discomfort, diarrhea, fever, loss of appetite for three (3) or more days, vomiting, jaundice; or 5. Has a pustular lesion such as a boil or infected wound that is: a. On the hands, wrists or exposed portions of the arms, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier; or b. On other parts of the body if the lesion is open or draining, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier.		

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14 Procedure when Infection or High Risk of Infection is Discovered

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When a person who may have handled pasteurized or aseptically processed milk or milk products or pasteurized or aseptically processed milk or milk product-contact surfaces meets one (1) or more of the conditions specified in the Administrative Procedures of Section 13, the Milk Regulatory Agency is authorized to require any or all of the following measures: 1. The immediate restricting of that person from duties that require handling pasteurized milk or milk products, or the handling of related milk or milk product-contact surfaces. This restriction may be lifted after an appropriate medical clearance or cessation of symptoms or both, according to the following Table:		
Removal of Restrictions when Infection or High Risk of Infection is Discovered **Health Status** — **Removing Restrictions** a. Is diagnosed with an illness due to Hepatitis A virus, *Salmonella typhi, Shigella* species, Norwalk and Norwalk-like Viruses, *Staphylococcus aureus, Streptococcus pyogenes,* — Restrictions lifted by medical clearance.		

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Escherichia coli 0157:H7, enterohemorrhagic *Escherichia coli,* enterotoxigenic *Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia,* Non-typhoidal *Salmonella*, Rotovirus, *Taenia solium, Yersinia enterocolitica, Vibrio cholerae* O1 or other infectious or communicable disease that has been declared by the Secretary of HHS to be transmissible to others through the handling of food or has been clearly shown to be so based upon verifiable epidemiological data.			
b. Meeting a high-risk scenario as specified in Section 13 (2 or 3) and/or experiencing symptoms in Section 13 (4 or 5).	Restrictions lifted when symptoms cease or medical documentation is provided that infection does not exist.		
c. Asymptomatic, but stools positive for *Salmonella typhi, Shigella* or *Escherichia*	Restrictions lifted by medical clearance		

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coli 0157:H7.			
d. Past illness from *Salmonella typhi, Shigella, Escherichia coli* 0157:H7 or other human pathogens for which humans have been determined to be carriers.	Restrictions lifted by medical clearance.		
e. In the case of diagnosed or suspected Hepatitis A, onset of jaundice within the last seven (7) days.	Restrictions lifted by medical clearance.		
f. In the case of diagnosed or suspected Hepatitis A, onset of jaundice occurred more than seven (7) days ago.	Restrictions lifted by medical clearance or jaundice ceases.		
2. The immediate exclusion of the affected milk or milk products from distribution and use when medically appropriate, i.e., a medical evaluation of the sequence of events indicates that contamination of milk or milk product may have occurred. 3. The immediate requesting of medical and bacteriological examination of the person at risk. **NOTE:** Persons at risk who decline to be examined may be reassigned to duties where they will not be required to handle pasteurized, ultra-pasteurized or aseptically processed milk or milk products and associated milk or milk product-contact			

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surfaces. In the case of milk plants, receiving stations, or transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, the HACCP System shall address the public health concerns described in this Section in a manner that provides protection equivalent to the requirements in this Section.		