

**A Brief Comparison of United States and European Union Standards for Fluid
Dairy Production**

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I. Introduction

The United States Veterinary Corps has the unique challenge of evaluating foreign food safety production systems and requirements to maintain safe food sources for the Department of Defense in overseas areas. The Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA) among other agencies perform this function in the United States to ensure that food safety standards are met to protect public health. Currently there do not appear to be well established procedures for determining fresh fluid milk safety equivalence¹ between the US and EU². European milk producers simply do not meet all of the U.S. requirements. Determining “equivalence” between U.S. and foreign food production standards, regulations, guidance and practice can be a substantial undertaking. When evaluating foreign food production standards, an analysis of the expected residual risk can be determined by utilizing established food safety auditing procedures. It is impossible to maintain the quantity and quality of sources required by the DOD if U.S. standards are applied verbatim in Europe. We cannot however compromise the health of the troops and their family members.

Section II of this paper will identify some of the primary differences in U.S. and EU herd health requirements. In section III, basic microbiological criteria in raw and finished product will be compared. Section IV will look at differences between the U.S. and the

¹ 62 Fed. Reg. 30593 (June 4, 1997) (*Fresh fluid drinking milk due to shelf life limitation is unlikely to be exported from the EU for US import*).

² CFSAN, *Affirmative Agenda for International Activities*, available at <http://www.cfsan.fda.gov/~comm/intlact.html> (Last visited Oct. 18, 2006).

EU definition of pasteurization. Section V will look at primary differences in equipment design criteria. Section VI will provide a review and recommendations to reduce or eliminate residual risk to maintain fluid milk approved source vendors for armed forces procurement in the European Theater.

II. Herd Health

A number of diseases may be transmitted from cattle to man by consuming milk products. Some of the diseases of concern include but are not limited to; tuberculosis, brucellosis, Q-fever, salmonellosis, staphylococcal infection and streptococcal infection. Disease causing organisms may get into the milk either directly from the udder, or indirectly through infected body discharges which may drop, splash or be blown into the milk during the collection process. Proper pasteurization normally achieves a 5 log reduction in the bacterial load significantly reducing or eliminating pathogens. By not utilizing positive reactor cows, greater assurance of public health protection is achieved by starting with what would be considered by many to be a safer product.

It appears that there are minor procedural differences in determining the herd health requirements as stated by the EU³ and the United States⁵. Many of the EU member states stringently regulate dairy herd health. In fact, many have integrated EU Directives into their own state laws. EU member states regulate dairy products in many different ways than what we are accustomed to in the U.S. For example; The Netherlands utilizes the COKZ. This organization, under government supervision, controls milk and dairy products. They enforce both national and international regulation, inspect, examine, issue export certificates, and enforce compliance among other functions. They are also

³ Corrigendum to Parliament and Council Regulation (EC) No 853/2004 O.J. (L 139).

responsible for monitoring herd health and utilizing EU Directives to supplement their own national laws⁴. The U.S. requires milk for pasteurization to be from herds essentially “officially free” from Tuberculosis and Brucellosis⁵ as certified or determined by the USDA. However, the EU requirement for herds to be free from these zoonotic diseases is only required for sale of raw milk direct to consumers⁶. EU Regulations allow milk obtained from herds that test positive for TB or Brucella to be used for pasteurized drinking milk⁷. The PMO prohibits milk from positive reactor cows to be used for drinking milk production. It is important to note that individual states in both the EU and the US may have their own regulations that are contrary but only effect inter community or interstate transfer of products. For example in the U.S. “In spite of 46 states adopting the PMO, it is at least technically possible to legally sell or distribute raw milk for human consumption in 32 states”⁸.

A. Recent Implementation of U.S. *MAP* Testing

A recent change in the U.S. has been the requirement that “all Grade "A" milk suppliers” join and participate in the USDA Voluntary Bovine Johne’s Herd Certification Program (VBJHCP) that promotes best management practices to eliminate or reduce the incidence of Johne’s disease in domestic cattle to the lowest possible level⁹. *Mycobacterium avium* subspecies *paratuberculosis* (MAP) is the causative agent of

⁴ See e.g., *Laws and Regulations*, available at <http://62.212.78.44/cokz/sites/web/default.asp?language=en>

⁵ FDA, *Grade “A” Pasteurized Milk Ordinance (PMO)*, § 8 113 (2005).

⁶ *Id.* art. L 139 (2004), Section IX, Chapter 1, 2.(a)

⁷ *Id.* art . L139 (2004), Section IX, Chapter 1, 3.(a)

⁸ See, e.g., Pete Kennedy, *An Overview of U.S. State Milk Laws*, Real Milk Articles, at <http://realmilk.com/milk-laws-1.html> (as of Dec 01, 2004)

⁹ See CAPT Robert F. Hennes, *National Conference on Interstate Milk Shipments*, pg. 150, available at <https://www.rs.uky.edu/sections/milk/ncims/IMS-a-45-FINAL.pdf> (Last visited Oct. 18, 2006).

Johne's disease, a chronic inflammatory bowel disease, in domestic cattle, sheep, goats and other wild ruminants; and Johne's disease is an internationally recognized disease of significant economic impact¹⁰. Milk containing *MAP* may be of particular concern because the bacterium has been suggested as a possible cause of Crohn's disease in humans. Recent studies have shown that *MAP* present in milk can survive currently utilized minimum time and temperature pasteurization combinations which have raised human health concerns"¹¹. Currently the EU Directives does not require monitoring of *MAP*.

III. Raw Milk Microbiological Requirements: EU & US

It is perhaps easiest to contrast the raw milk microbiological requirements of the US and EU as I have illustrated in the following table.

Table 1. Limits on bacterial levels in milk (cfu/ml)		
Raw milk for production	EU	US
Bacteria (SPC)	<100,000	<100000 ¹ / <300,000 ²
Drugs/ml	<0.004µg ^{12, 13}	None detectable
Pasteurized milk		
Bacteria (SPC)	5 000/50 000	<20 000
Enterobacteriaceae	5	
Coliforms	5	<10

¹ Individual Producer, ² Commingled Milk

¹⁰ See Wikipedia, *Mycobacterium avium and MAP*, http://en.wikipedia.org/wiki/Mycobacterium_avium_subspecies_paratuberculosis (last visited Oct. 21, 2006)

¹¹ Li L; Bannantine JP; Zhang Q; *et al.* (2005). "The complete genome sequence of *Mycobacterium avium subspecies paratuberculosis*". *Proc Natl Acad Sci.* 102: 12344–12349 available at <http://www.pnas.org/cgi/reprint/102/35/12344.pdf> (last accessed Oct.21, 2006).

¹² EEC No 2377/90 (1990), Annexes I and III, (*The combined total of residues of all substances may not exceed a value to be fixed in accordance with the procedure laid down in Regulation*).

¹³ J. Hillerton and E. Berry, *Quality of the Milk Supply: European Regulations Versus Practice*, Institute for Animal Health, Compton, United Kingdom available at <http://www.nmconline.org/articles/qualityeuro.pdf>

Much of the reason for performing microbiologic testing of raw milk is to help determine the raw product quality. However, pasteurization systems are designed to provide a 5 log reduction of the microbial load using the most thermo-tolerant target pathogen *Coxiella burnetii*¹⁴. Starting with a lower bacterial load does provide better assurance that pathogenic bacteria and spoilage organisms present in raw milk will be destroyed during pasteurization, thereby significantly increasing safety and shelf life. Post pasteurization testing normally looks for organisms that could indicate post-pasteurization contamination or incomplete pasteurization. Processing with heat has little to no effect on antibiotics. Both the US and EU milk is required to be essentially free from detectable quantities of drugs.

From a risk analysis point of view appears to be no substantial difference between the EU and U.S. standards.

IV. Definitions

The definitions of pasteurizing, pasteurized, and similar terminology concerning milk seem to differ in description between the U.S. and EU. In the US "pasteurization," "pasteurized," and similar terms shall mean the process of heating every particle of milk and milk product in properly designed and operated equipment to specified time and temperature combinations¹⁵. Equipment design and operation standards are specified in the PMO that references 3-A sanitary engineering standards.

The EU definition seems far less specific. The EU requires HACCP to be employed and has very little specificity for equipment engineering design or proper operation. EU

¹⁴ CDC, *Viral and Rickettsial Zoonoses Branch*, available at <http://www.cdc.gov/ncidod/dvrd/branch/vrzb.htm> (last visited Oct. 28, 2006)

¹⁵ 21 CFR § 131.3(a); 21 U.S.C. § 321(s)

Directives require pasteurized milk to test negative for alkaline phosphatase¹⁶. The phosphatase test is an index commonly utilized in the dairy industry to determine pasteurization efficacy¹⁷. Phosphatase testing in the US is required by the PMO at least once per month. In the EU it is common to perform this test only once after installation of the equipment to meet this requirement as there is no specified frequency.

Time and temperature combination specified by the PMO, CFR and Codex¹⁸ all require specific minimum time and temperature applications. I have yet to encounter a single European facility that utilizes the minimum the required time and temperature combinations. Most utilize divert flow triggers greater than 72 degrees Celsius.

The most significant difference in definitions between the U.S. and EU is the U.S. wording such as “every particle” and “properly designed and operated equipment”. The European Hygiene Equipment and Design Group (EHEDG) defines pasteurization as a microbiocidal heat treatment aimed at reducing the number of any harmful microorganisms, if present, to a level at which they do not constitute a significant health hazard¹⁹.

IV. Equipment Design

Dairies in the United States producing fresh fluid drinking milk are regulated to the extent that pasteurization equipment must be engineered and built to exact specifications, is tested and even locked or sealed by health authorities. This is not the case in European Union dairies. European dairies are given much greater flexibility in design and are not

¹⁶ *Id art.* Regulation (EC) No 853/2004 (2004), Section IX, Chapter 1, 3.(a)

¹⁷ *Id.* Grade “A” Pasteurized Milk Ordinance, (2005 revision), Appendix G. Section II. pg. 200

¹⁸ See CODEX, *Code of Hygienic Practice for Milk and Milk Products, CAC/RCP 57–2004*, pg 38.

¹⁹ European Hygiene Equipment and Design Group Glossary (2004) available at <http://www.ehedg.org/glossary.pdf#search=%22EHEDG%20milk%20pasteurization%22> (last visited Oct.21, 2006).

required to seal equipment. The Grade “A” Pasteurized Milk Ordinance (PMO); administrated by FDA outlines design, engineering requirements and 3-A Accepted Practices. In the U.S., the FDA or qualified state inspector must verify that pasteurizers are designed and installed in accordance with specific criteria outlined in the PMO. Testing is conducted at a set frequency and seals affixed to controls that could manipulate the time, temperature, or pressure differential required to meet established regulations.

The European Hygienic Design Group (EHEDG) is the primary organization for food equipment approval in Europe. Guidelines for the construction and design of food processing equipment rather than standards are presented by EHEDG. Acceptance for food processing equipment used in some European countries seems to be based primarily on the ability to clean and sanitize effectively²⁰.

A. Frequently Identified Design Differences

There appear to be a few primary differences between how the U.S. and EU regulate milk production equipment design and operation. Pasteurization systems in the US are designed to specific standards and are verified by regulatory authorities prior to, and on a scheduled frequency after milk is produced and offered for interstate commerce. Proposed deviations to established engineering standards must be presented and proven to be effective prior to use. In the EU there are design standards that are referenced but do not seem to be enforced. Basic design guidance by EHEDG goes undetected, ignored or is not enforced by EU member state regulators. Many European dairies use a High Heat Short Time (HHST) system with High Temperature Short Time (HTST) times and temperatures and other hybrid type systems. From an engineering standpoint, this

²⁰ European Hygienic Equipment Design Group *available at* www.ehedg.org (last visited Oct. 20, 2005).

eliminates need for static pressure controls such as balance tank, free draining of heat exchanger, and vacuum breakers. In Europe, the three most commonly identified deviations from U.S. design criteria are the holding tube, pressure differential requirements, and testing requirements. Holding tubes are designed to provide a known time that milk is maintained over a specified temperature. The PMO requires holding tubes to slope upward (2.1 cm per meter) to preclude air entrapment and ensure uniform product flow. EHEDG guidance is that holding tubes should slope upwards from bottom to top. The great majority of U.S. Army audited establishments reveal holding tubes having no slope or an irregular slope. Examples of an acceptable (figure 1) and an unacceptable (figure 2) holding tubes are pictured below.



(Figure 1) PMO Standard



(figure 2) Common in EU Facilities

The PMO requires a positive pressure differential be maintained on the pasteurized milk side in the regenerator to prevent intermixing should there be holes in the plates separating raw and pasteurized milk. Higher pressure of at least one pound per square inch is verified using pressure monitors that are inter-wired with the divert mechanism. The EHEDG advocates pressure testing and inspection of regenerator plates in lieu of maintaining higher pressure on pasteurized side of regenerator but no monitoring of pressure differential or inter-wiring with the divert valve is required. Thermometer redundancy is another primary area of difference. The PMO requires an indicating

thermometer at the end of the holding tube and a separate recording thermometer. In the EU, only a recording thermometer is specified. This practice does not allow for operators to verify thermometer accuracy except when it is removed from the system and calibrated. Further, in the EU there is no set requirement for thermometers used on pasteurizers to be calibrated at a specific frequency.

Conclusions

The DOD can not wait for CFSAN to evaluate equivalence of EU dairy safety systems as one of their 2006 priorities²¹. I recommend that contractual requirements specify that raw milk be obtained from localities having and enforcing PMO/USDA equivalent requirements, including allowing raw milk to be obtained only from herds that the local regulatory authority certifies as being free from brucellosis and tuberculosis to minimize the risk of transmission. Currently, each of the four countries DOD purchases fresh fluid drinking milk from utilizes herd stock designated free from Brucellosis and Tuberculosis²².

Microbiological requirements between the EU and U.S. are not significantly different. Pasteurizer engineering, design and operation differences can be evaluated during routine food safety audits by Phase IV qualified Veterinary Corps auditors²³ to ensure food safety risks are satisfactorily mitigated.

²¹ CFSAN (2006) Program Priorities, *letter from the center director dated May 3, 2006 available at <http://www.cfsan.fda.gov>* (last visited Oct. 20, 2006).

²² *Veterinary Health Declaration Certificates Received from Supplying Host Nation Veterinary Authority, maintained on file at the 100th Medical Detachment Veterinary Services Headquarters Heidelberg Germany.*

²³ Department of the Army, MEDCOM Pamphlet No. 40-13 Medical Services, *U.S. Army Veterinary Command Guidelines and Procedures*, dated 13 Feb. 2006, available at <http://www.dscp.dla.mil/subs/support/qapubs/medcom/40-13.pdf> (last visited Feb. 22, 2006)

My experience performing over 300 food safety audits in Europe has allowed me to see a great number of pasteurizer designs. No single facility met all of the sanitary design and engineering requirements of the PMO. However, many facilities (particularly those supplying the Department of Defense have integrated many of the design and engineering principles of the PMO into their operations such as holding tube slope, pressure differential monitors and inter-wiring, thermometer redundancy and calibration frequency. We should continue to utilize Military Standard 3006, HACCP and the PMO as a guide for individual evaluations of fresh fluid milk providers. These documents and principles coupled with supplemental specific contractual requirements should fill the gaps between EU and member state fluid dairy safety regulation so that U.S. Forces and their family members overseas may continue to enjoy safe, high quality milk. Due to the drawdown of U.S. Forces in the European Theater, we should not require additional sources be approved and directory listed in accordance with Army Regulation 40-657. The key to managing food safety of fluid dairy remains with utilizing only qualified auditors to evaluate each supplier on a case by case basis. I do not foresee allowing a blanket policy to remove auditing requirements of fresh fluid milk producers in the EU due to the perceived gaps in regulation.