



United States
Department of
Agriculture

Agricultural
Marketing
Service

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Room 2968-S, STOP 0225
Washington, DC 20250-0225

Frequently Asked Questions Regarding the European Union Health Certification Program January 6, 2012

Milk Quality Requirements

1. **Is it illegal to sell milk in the U.S. with somatic cell counts that exceed 400,000 cells/mL?** No, the regulatory limit for somatic cells counts in milk is 750,000 cells/mL as established by the Pasteurized Milk Ordinance (PMO). Some states set standards that are more stringent than the PMO. Milk with a rolling mean somatic cell counts greater than 400,000 cells/mL cannot be certified for export to the European Union (EU) unless a derogation is requested from AMS. The AMS Dairy Programs EU certification program is voluntary and only applies to milk and milk products that are exported to the EU member countries.
2. **How should the monthly milk quality records be established for each farm?** To establish monthly milk quality farm records at least one milk sample per month must be tested for Somatic Cell Count (SCC) and two samples for Bacterial Standard Plate Count (SPC). A milk supplier may also use an average of a number of samples taken at the farm during the month. AMS will accept the counts used to establish payments for the farm milk. AMS will also accept regulatory sample tests provided that the minimum numbers of samples are taken.
3. **Will monthly SPC test results be required for verified Grade A milk producers?** No, SPC tests data will only be required for Grade B milk farms. Grade B farms will be given two months to establish an initial rolling two months means for SPC. The U.S. regulatory SPC requirement for Grade A milk is equivalent to the EU regulation of 100,000 bacterial per mL.

Milk Supplier's Responsibilities

4. **What unique information must a milk supplier provide on each Certificate of Conformance (COC)?** The milk supplier shall have records of individual farms available to link and confirm that raw milk meeting the EU requirements for SCC and SPC is received at the facility manufacturing dairy products for shipment to the EU.
5. **What are the responsibilities of the milk supplier when the farm's rolling mean exceeds the maximum EU requirement?** A milk supplier must notify AMS if a farm's rolling mean exceeds the EU requirement and the milk is used for products that are certified for export to the EU. If the farm comes back into compliance no further notification is needed. If the farm exceeds the

requirement for three consecutive months after notification then the plant must ask for a derogation or exclude the milk from entering products shipped to the EU.

6. **Provide an example of the timeline before a farm would be considered out of compliance. This would be the time when the milk supplier must make decisions about the use of milk from that farm. See Table Below:**

**Determining Compliance Eligibility for European Union Export Certification
Effective January 1, 2012**

Month	Monthly data for rolling three-month mean for SCC	If result of rolling three-month mean for SCC	Actions
April, 2012	Jan, Feb, Mar	> 400,000	Milk ok for export in April. Notify AMS.
May	Feb, Mar, Apr	> 400,000	Milk ok for export in May. (1st month)
June	Mar, Apr, May	> 400,000	Milk ok for export in June. (2nd month)
July	Apr, May, Jun	> 400,000	Milk ok for export in July. (3rd month)
August	May, Jun, Jul	> 400,000	<u>Milk NOT ok for export in August.</u> Milk supplier must suspend, segregate, discontinue certification or request derogation from AMS to be eligible.

AMS requires the milk supplier to request a derogation or exclude the milk from EU certification when they receive the July numbers in early August. AMS will accept derogations and apply them retroactively if the plant makes the request in a reasonable time frame.

7. **Will the COC for farm milk collected in a given month be used to determine compliance in following month?** Yes, a COC covering raw milk delivered in April would be based on March's compliant three-month rolling mean. This avoids a milk supplier having to trace product that may have moved significantly through the supply chain before the monthly sample is analyzed and reported.
8. **What unique information must a milk processor or applicant provide on each Certificate of Conformance (COC)?** The processor shall have records for dairy ingredients or composite food that require an EU Health Certificate. There must be enough information to trace back at least one step toward the raw milk production for milk or dairy products covered by the COC for verification during the AMS Dairy Programs review of records. This can include production lot identification codes, production dates, bills of lading or any other documentation that provides this information. It will not detail individual farms.
9. **Is it possible for a farm to be out of compliance for either the SPC or the SCC requirements or for both requirements?** Yes, derogations are specific to the parameter(s) (SCC or SPC) that is out of compliance. A farm could conceivably have two derogations at once. The requirements are mutually exclusive.

Derogations

10. **What is a derogation?** A derogation is a deviation under special circumstances to allow the milk in question to be accepted into the EU export certification program. A derogation will be granted provided that during the processing of milk or milk products they are (i) pasteurized or (ii) made into raw milk cheese that will be aged at least 60 days before being placed on the market. While a farm is under a derogation, testing of the farm samples are expected to continue.
11. **When is a seasonal derogation granted?** AMS will base seasonal derogation on the farm being in compliance 9 months of the year. The purpose of a seasonal derogation is to recognize a farm that has satisfactory production methods may still not be able to meet the requirements during certain seasonal periods due to circumstances outside the control of the farm. Seasonal derogations must be caused by a seasonal phenomenon (for example: temperature, seasonal rains) and not by poor sanitation, hygiene or animal husbandry practices. Seasonal derogations must be renewed every three years.
12. **What information is required when requesting a derogation?** The following information must be provided when requesting a derogation: name of requester; phone number; e-mail address; the name, city, state, plant number and customer (Applicant Number) of milk supplier requesting the derogation; the information for the farm needing the derogation (name of the farm, location and patron identifier); the month of year the derogation is being requested and the counts for that farm (three months records for a standard derogation or 12 months for a seasonal derogation.)
13. **What records or data will AMS recognize to support a request for a seasonal derogation?** A request for seasonal derogation must be supported by legitimate records such as DHIA or processor data and milk check information (at least 12 month's records) and be consistent with the expected seasonal variations for the area. Seasonal derogation requests that do not correspond with normal seasonal variations will not be granted.
14. **How long is the derogation approval process expected to take?** AMS expects most standard (non-seasonal) derogations to be granted within 5 business days. Seasonal derogations may take longer. Derogations must be requested via E-mail. Each request will be reviewed by AMS supervisory staff. AMS will accept derogations and apply them retroactively if the plant makes the request in a reasonable time frame.
15. **What are the conditions under which a derogation renewal would be denied?** AMS would deny a derogation application if there was no apparent effort to bring the farm into compliance during the previous derogation and renewal of the derogation would be detrimental to the EU certification program.

Review of Records

16. **Who is financially responsible for the incurred charges during the review of records?** The applicant who requested the export certificate is the responsible party.
17. **How will documentation be utilized to trace back to the producer?** AMS will review 10% of the milk supplier's farm records. A COC must accompany each transfer of milk or dairy products through the supply chain. The COC on file from each supplying plant must have records to support that each lot in question meets EU requirements for SCC and SPC. AMS will conduct a review to trace back at least one continuous line of production from exported product to farm milk source.
18. **How long must records be retained for review purposes?** Records documenting compliance must be kept a minimum of 12 months or since the last review, whichever is longer. Retention of records shall not be required beyond 3 years.

Fees

19. **What are the fees assessed for each issued derogation?** AMS will charge the milk supplier an administrative fee of two hours at the current *Federal Register* published rate for Dairy Programs services for each derogation (seasonal or otherwise) application. (As of January 1, 2012, the rate is \$68.00 per hour. The fee for the derogation would be \$136.00.)

The official EU Health Certification Program document may be found at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5096347>

If additional questions arise regarding this program, please contact Ken Vorgert, Chief, Dairy Grading Branch at 630-437-5037; email Ken.Vorgert@ams.usda.gov or Diane Lewis, Director of Grading and Standards Division at 202-690-0530; Diane.Lewis@ams.usda.gov.