Frequently Asked Questions (FAQ)
AMS Dairy Program European Union Health Certificate Program

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Program Guide: Frequently Asked Questions AMS Dairy Program European Union Health Certificate Program
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Program Applicability and Scope

What countries require this program?

The EU countries, the EU aligned countries identified in the tables below and the United Kingdom and Turkey.

List 1: European Union 27 countries

Austria	Estonia	Italy	Portugal
Belgium	Finland	Latvia	Romania
Bulgaria	France	Lithuania	Slovakia
Croatia	Germany	Luxembourg	Slovenia
Cyprus	Greece	Malta	Spain
Czechia	Hungry	Netherlands	Sweden
Denmark	Ireland	Poland	

List 2: European Free Trade Association (EFTA) countries accepting EU certificates

Iceland	Liechtenstein	Norway	Switzerland

What products are impacted by this program?

Any dairy product or composite product containing a dairy ingredient that is destined for the EU market, Great Britain, or Turkey. A composite product is defined as a food containing both processed products of animal origin and products of plant origin.

Are products transiting through the EU to other countries or military installations impacted by this program?

Yes, however, dairy products and composite products containing dairy ingredients are subject to less stringent requirements when the product(s) is transiting through the EU and not intended to be consumed by EU consumers. In general, transit certificates are only applicable to the EU.

What firms within the U.S. dairy industry supply chain are impacted by this program?

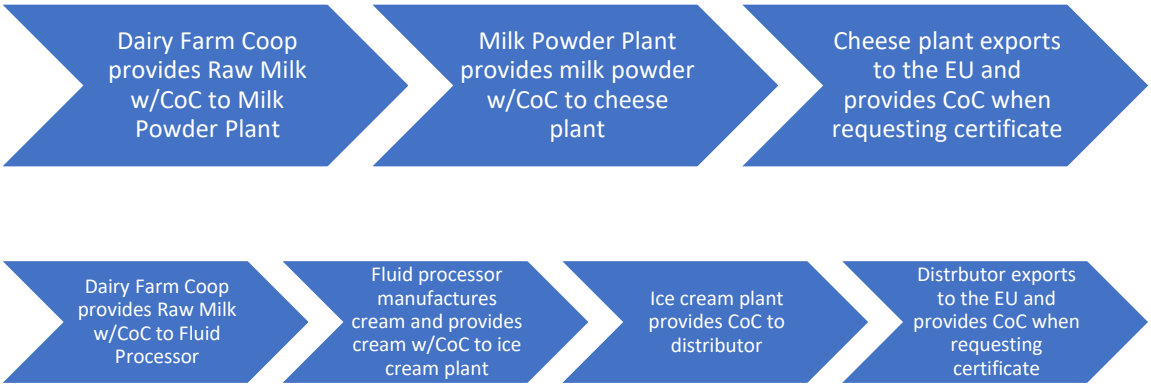
All firms within the supply chain are impacted by the EU requirements. Each firm/organization within the supply chain must demonstrate the dairy products/ingredients included in each product destined to the EU, was manufactured using dairy products/ingredients derived from milk sources meeting the EU requirements. Compliance with these requirements can be demonstrated through use of a Certificate of Conformance (CoC), coupled with other documents such as shipping records, bills of lading, manifests, production records, etc. Records must also be maintained to verify the raw milk was supplied by credentialed (permitted/licensed) farms regulated either under the requirements of the Grade 'A' Pasteurized Milk Ordinance (PMO) or the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements.

What is a CoC?

The CoC attests the dairy product/ingredients used in the food product destined to the EU, are in compliance with the EU requirements. As an example:

- Milk Supplier: The milk supplier (coop or other supplier of raw farm milk) provides a CoC to the dairy processor attesting the raw milk meets the EU milk quality requirements and the raw milk was supplied by credentialed (permitted/licensed) farms regulated either under the requirements of the Grade 'A' Pasteurized Milk Ordinance (PMO) or the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements.
- Dairy processor: Dairy processors use the milk supplier CoCs to either determine all of their raw milk sources meet the EU requirements or to segregate production so a portion of their dairy products produced meet the EU requirements. Subsequently, the dairy processor provides a CoC to the next actor in the supply chain to verify the dairy product/ingredient meets the EU requirements.
- Subsequent dairy or food processor(s): If applicable, the subsequent dairy or food processor will use the CoC(s) from dairy product/ingredient suppliers to ensure all dairy products/ingredients used in their products meet the EU requirements. This will allow for the subsequent dairy or food processor to provide a CoC attesting the dairy ingredients used to manufacture their food product(s) meet the EU requirements.
- Applicant or Exporter: The firm or organization requesting an EU health certificate is referred to as the applicant for the health certificate. The applicant may be a dairy processor, subsequent dairy or food processor or a broker/distributor. Regardless, the applicant will need to ensure a CoC is available from the previous actor within the supply chain. This will allow the applicant to provide a CoC attesting the dairy or food product was manufactured with dairy ingredients meeting EU requirements. The CoC will be submitted electronically when the applicant requests the EU, Great Britain or Turkey health certificate.

Figure 1: Example Illustration of CoC provided throughout the supply chain.



Milk Quality Requirements

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 in the United States as established by the Pasteurized Milk Ordinance (PMO). Some States set standards that are more stringent than the PMO. The regulatory limit for somatic cell counts in the EU is 400,000 cell/ml. Milk with a rolling mean somatic cell count 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 Program EU Export Verification Program (EU-EVP) is voluntary and only applies to milk and milk products that are exported to the EU member countries.

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 farm, 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 ofsamples are taken.

See Appendix 1 for an example of a timeline before a farm would be considered out of compliance.

Will monthly SPC test results be required for verified Grade A milk producers?

No, SPC test 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 mean for SPC. The U.S. regulatory SPC requirement for Grade A milk is equivalent to the EU regulation of 100,000 bacteria per ml.

Milk Supplier's Responsibilities

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 the raw milk meeting the EU requirements for SCC and SPC and the raw milk was supplied by credentialed (permitted/licensed) farms regulated either under the requirements of the Grade 'A' Pasteurized Milk Ordinance (PMO) or the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements.

What type of information will be review for the EU-EVP to determine if the CoC's for the milk supplier meet the requirements?

CoCs provided by milk suppliers to processors will be reviewed to determine they meet appropriate time frames for raw milk supplies provided to a specific processor. Additionally, laboratory test records for individual farms will be reviewed to determine the SCC and SPC results meet EU requirements. Determination as to whether each farm supplying the plant is a credentialed (permitted/licensed) farms regulated either under the requirements of the Grade 'A' Pasteurized Milk Ordinance (PMO) or the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements will be determined during the laboratory record review, evidence may include farm permits/licenses, farm inspection records, or other records to verify farm milk production under one of these programs.

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 month then the plant must ask for aderogation or exclude the milk from entering products shipped to the EU.

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.

Will the CoC for farm milk collected in a given month be used to determine compliance in the 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.

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

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 verification program. A derogation will be granted provided that during the processing of milk or milk products they are (i) pasteurized or (i) 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. Derogations must be renewed every year if the farm continues to fall outside of the EU requirements.

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 and may still not be able to meet the requirements during certain seasonal periods due to circumstances outside the farm's control. 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.

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.)

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.

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-Docs. 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.

What are the conditions under which a derogation renewal would be denied?

AMS will deny a derogation application if there is 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.

Dairy and Food Processor Responsibilities

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 Program review of records. This may include production lot identification codes, production dates, bills of lading or other similar information. It will not detail individual farms. An example of the COC can be found in the EU Health Certificate Program document underExhibits 1.B.1 and 1.B.2.

A Dairy or food processor's CoC(s) issued for their product(s) should, at a minimum, include:

- A clear statement the dairy product(s)/dairy ingredient(s) were produced under a system that results in compliance with EU requirements.
- The dates or lot codes the dairy product(s)/dairy ingredient(s) (covered the CoC) were processed,
- The location where the documents of compliance can be found,
- The signed and printed signature of the individual who is authorized to attest to these statements, and
- A date when the processor's CoC was signed.

What if a dairy or food processor uses imported dairy ingredients?

Dairy or food processors utilizing imported dairy products and dairy ingredients intended to be used for the production of products that will be shipped to the EU must:

- Ensure the manufacturing facility is on the EU Third Country Establishment approved dairy facility list for the country origin, and
- Present a certificate issued by the competent authority of the country of origin certifying these imported dairy products and ingredients meet EU requirements.

EU-EVP Review of Records

Who is financially responsible for the incurred charges during the review of records?

The firm or organization being audited is responsible for audit fee charges.

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.

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. These records must be accessible during the AMS Dairy Program record review. Retention of records shall not be required beyond 3 years

What records will be reviewed?

Records to document compliance with EU requirements include but may not be limited to:

Broker/Applicant Auditee documents to review:

- Applicant's Certificate of Conformance
- Health Certificate(s)
- Animal Health Certificate(s) and show proof that the EU dairy materialized is on the EU export approved dairy list.
- Production records
- Distribution records / Shipping records
- Certificate of Conformance(s) from Manufacture/Processor tracing one step back towards the raw milk supplier.

Manufacturer/Processor Auditee documents to review:

- Processor of Dairy Ingredients' Certificate of Conformance
- Ingredient/packaging materials supplier requirements/receiving procedures
- Batch identification procedures
- Production records
- Distribution records / Shipping documents
- Certificate of Conformance(s) from Milk Supplier tracing one step back towards the raw milk supplier.

Milk Supplier Auditee documents to review:

- Milk Supplier's Certificate of Conformance
- Ingredient/packaging materials supplier requirements/receiving procedures
- Batch identification procedures
- Raw milk production records: Totals for the Grade A and Grade B farms, SCC & SCC milk records, notifications, derogations, rolling mean, rolling geo-metric mean.
- Distribution records / Shipping documents

Transit Certificates

What are the requirements for transit certificates?

Shipments transiting the EU to third countries or to US military installations in the EU, require transit certificates and only require that animal health attestations requirements are met for the EU. This means the human health attestations relating to the SCC and bacterial SPC requirements are not applicable. Please note, even though the SCC and bacterial SPC requirements are not required to be met for transit certificates, exporters and others within the dairy ingredient supply chain will still be required to maintain a CoC to demonstrate the raw milk was supplied by credentialed (permitted/licensed) farms regulated either under the requirements of the Grade 'A' Pasteurized Milk Ordinance (PMO) or the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements.

Additionally, there is more flexibility relating the dairy manufacturing plants supplying the dairy product(s)/ingredients for products transiting the EU. The manufacturing plant(s) supplying the dairy ingredient(s) for the final product for export may either be included on the EU dairy export list; or be regulated by the U.S. regulatory agency. If the manufacturing plant supplying the dairy ingredient is not on the EU dairy export list, the plant will be validated against U.S. regulatory lists such as the Interstate Milk Shipments (IMS) list, USDA approved plant list or FDA's Establishment Identification (FEI)FEI number list.

Transit certificates will be subject to a less stringent EU-EVP record review process to simply verify the raw milk sourced for applicable dairy ingredients was supplied by Grade 'A' Pasteurized Milk Ordinance (PMO) or the USDA AMS Milk for Manufacturing Purposes credentialed farms. These records must be maintained for a minimum of 12 months after the date of shipment or since the last review, whichever is longer. Retention of records shall not be required beyond three years. These records must be available during an AMS Dairy Program EU-EVP record reviews.

Fees

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 Program services for each derogation (seasonal or otherwise) application. (As of October 1, 2021, the fee for the derogation is $123.00)

Additional Resources

The official EU Health Certification Program document may be found at EU Dairy Export Certification Programs.

Agency Contacts

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Appendix 1.

Determining Compliance Eligibility for European Union Export Certification Effective January 2, 2012

Month	Monthly data for rollingthree-month mean for SCC	If result of rolling three-month mean for SCC	Actions
April	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	Milk NOT ok for export in August. Milk supplier must suspend, segregate, discontinue certification or request derogation from **AMS** to be eligible.

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