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AMS DAIRY PROGRAM DAIRY GRADING BRANCH

European Union (EU) Export Verification Program (EVP) (EU-EVP)

Eligibility for USDA AMS Dairy Export Health Certificates to the EU

Dairy Grading and Standardization Division

Current Version

03/26/2024

Previous Versions

01/05/2021

07/01/2022

10/25/2023

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Introduction:

These instructions establish the responsibilities and procedures for maintaining eligibility for obtaining European Union Health Certificates (hereafter referred to as “EU health certificate”). The program outlined in these instructions shall be used to demonstrate compliance with Regulation (EC) No 853/2004, Regulation (EC) No 853/2004, Implementing Regulation (EU) 2019/627, Regulation (EU) 2016/429, Commission Delegated Regulation 2020/692 and Commission Implementing Regulation (EU) 2020/2235. These and other EU regulations outline the requirements for the export of dairy products from the United States to the EU.

At the time of this issuance, there are 27 country members of the EU importers as identified in **Table 1** below.

Table 1: European Union 27 Countries

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

In addition, the following member countries of the European Free Trade Association (EFTA) accept EU certificates:

Table 2: European Free Trade Association (EFTA) Countries Accepting EU Certificates

Iceland	Liechtenstein	Norway	Switzerland
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The requirements outlined in this document also demonstrate compliance with health certificates requirements for Somatic Cell Count (SCC) and Standard Plate Count (SPC) requirements for [Great Britain](#) and [Turkey](#).

Audience:

The audience for this document is industry stakeholders involved in all stages of the supply chain for the export of dairy products and composite products containing dairy ingredients to the EU, Great Britain and Turkey.

Scope and Products Covered:

The requirement to provide an EU health certificate is controlled by the importing country or port authority within the EU. Generally, all dairy products readily recognized as a dairy product or require in

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the product's standard of identity that milk or dairy products originate from milk from cow, buffalo, sheep, goat or "females of other species belonging to herds", will require an EU health certificate and are covered by this program.

Composite products containing dairy ingredients are also covered by this program. The EU defines a composite product as a food containing both processed products of animal origin and products of plant origin. The animal origin products covered by the EU requirements for composite product certificates include dairy products, egg products, fishery products and meat products. If the composite product contains a dairy product ingredient, this export verification program is applicable. Please note, export verification programs for other animal origin ingredients (egg, fishery, and meat products) may also be applicable.

The rules for composite products have significantly changed. De minimis thresholds have been replaced by complex risk-based criteria (e.g., shelf stable vs non shelf stable). Exporters are urged to review additional guidance from multiple sources to verify the type of certificate needed to export to the EU. Applicants may contact their importer to determine if a certificate is needed and/or of any other unique requirements. Links to EU references on composite products include:


[EU import conditions for composite products](#)

[Import of composite products into the EU Questions & Answers Version November 7, 2023.](#)

Dairy Establishment Listing Requirement:

For many products of animal origin, including milk and dairy products, the EU will only accept imports originating from third country establishments that appear on the EU's lists of third country establishments from which imports of that product are permitted. The EU maintains the lists of approved establishments based on submissions from the competent authorities of exporting countries. The U.S. Food and Drug Administration (FDA) is the U.S. competent authority for milk and dairy products. The EU's list of approved third country establishments is divided into [several sections for food products](#). The list for approved dairy manufacturers is identified by the EU as the Approved Establishments list for the U.S. for "*Raw milk, dairy products, colostrum and colostrum-based products*" approved for export to the EU. FDA refers to the EU's lists for these products as the "List of U.S. Establishments Eligible to Export Dairy Products to the EU." Establishments involved in the production of milk or dairy products may apply with FDA to be included on these lists via the FDA [Export Listing Module](#).

Please note that relevant establishments must be officially listed by the EU for products to be eligible for entry. FDA sends the EU updates to these lists on a quarterly basis, but it may take considerable time for the EU to publish the updated lists. Please consult the official lists posted on the EU Integrated Management System for Official Controls/Trade Control and Expert System (IMSOC/TRACES) [EU IMSOC TRACES website](#) to ensure the relevant establishment is listed by the EU before attempting to request an EU health certificate.

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Dairy plants supplying dairy product(s) or dairy ingredient(s) to an EU health certificate applicant but do not ship dairy product directly to the EU may be required to be listed if their product is used as an ingredient in a dairy or dairy composite product shipped to the EU. All firms on the Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU will be subject to AMS Dairy Program record reviews (hereafter referred to as EU Export Verification Program) (EU-EVP) to verify compliance with EU SCC and bacterial SPC requirements as well as other EU requirements. At the same time, the AMS Dairy Program will verify the U.S. milk used for products exported to the EU is sourced from establishments regulated under either the [Grade ‘A’ Pasteurized Milk Ordinance](#) or the [USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements](#) program. Entities throughout the supply chain are expected to maintain records to demonstrate that milk used for export to the EU was sourced from farms regulated under one of these programs. Record keeping requirements may be met by maintaining a Certificate of Conformance (CoC) (described later in this document) on file for dairy ingredients used within the dairy product or dairy composite product.

EU Regulations for the requirements for Dairy Products Imported into the EU

The requirements for dairy products imported into the EU are detailed in several EU regulations including Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, Implementing Regulation (EU) 2019/627, Regulation (EU) 2016/429, Commission Delegated Regulation 2020/692 and Commission Implementing Regulation (EU) 2020/2235. These comprehensive regulations address many issues relative to milk production, processing, and product export certification. Other countries outside of the EU that import dairy products to this market are also required to provide certificates indicating compliance with these regulations.

Milk produced and dairy products manufactured under the U.S. regulatory system provide safeguards at least equivalent to the requirements of the above related regulations. However, there are two quality- related differences between the two systems (these differences are not applicable for colostrum):

- 1) The EU SCC and bacterial SPC requirements that apply at the farm level and;
- 2) The method for calculating SCC and bacterial SPC averages (rolling geometric mean). To certify dairy product shipments to the EU, AMS Dairy Program requires dairy product manufacturers to certify compliance with the SCC and/or bacterial SPC requirements of Regulation (EC) No 853/2004. The requirements are as follows:
 - The maximum SCC in raw cow’s milk for the production of heat-treated milk, milk products and other milk-based products is 400,000 SCC per ml.
 - The maximum bacterial SPC for raw cow’s milk for the production of heat-treated milk, milk products and other milk-based products is 100,000 bacteria per ml.

Grade ‘A’ cow’s milk and Milk for Manufacturing (Grade B) cow’s milk in the U.S. are regulated at maximum SCC of 750,000 per ml. Grade ‘A’ milk in the U.S. is regulated at a bacterial SPC of 100,000

per ml or less. The recommended regulatory bacterial SPC for Milk for Manufacturing (Grade B) cow’s milk in the U.S. is 500,000 per ml or less. Testing of the farm-level milk supply will be necessary to document compliance with the EU requirements for shipment of dairy products to the EU (both Grade ‘A’ and Grade B milk for SCC-and only Grade B milk for bacterial SPC). Plants with a Grade ‘A’ milk supply that supply ingredients or raw milk are generally exempt from requirements to keep additional records on bacterial SPCs to confirm compliance with Regulation (EC) No 853/2004.

Categories and Descriptions of Entities for EU Export Verification

Category	Description
Applicant (exporter or consignor)	An entity submitting a request for an EU Health Certificate. An applicant could be a manufacturer, broker or other entity exporting goods.
Composite Product Processor/Manufacturer	Processor/Manufacturer of composite product (food product containing both processed products of animal origin and products of plant origin. This includes composite products containing any amount of dairy ingredients).
Dairy Processor/Manufacturer	Processor/Manufacturer of dairy product(s) being exported or used as an ingredient in another dairy product or in a composite product for export to the EU.
Milk Supplier	The supplier of milk used in the manufacture of the product(s). For example: cooperative, direct shipper, milk shipper (the entity with farm records), proprietary processor, dairy milk marketer, etc.

The applicant for the EU health certificate, the processor(s) and the milk supplier(s) involved in the production of the product certified for shipment to the EU must maintain records documenting compliance with EU SCC and bacterial SPC and that 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 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.


Responsibility of Applicants

Applicants must request the EU Health certificates through the [ATLAS platform](#) and agree to the attestation statements presented prior to application submission:

Attestations:

The following statements are required in the ATLAS application:

- I certify the above product is for human consumption.
- I certify the entity I am submitting an application for is NOT delinquent on any USDA Payments.

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- I certify the entity that I am submitting an application for is approved to export items to the country specified.
- I acknowledge by clicking this box the information is factual and accurate.
- I certify that all of the dairy products and/or dairy ingredients used for the production of the products included in the application were produced from:
 - Raw milk meeting the SCC (400,000 per ml.) and bacterial SPC (100,000 per ml.) requirements of the European Regulation (EC) No. 853/2004.
 - 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
- I acknowledge responsibility for maintaining adequate records to trace the production and CoC for all dairy products and/or ingredients used in the products presented for certification one step back in the supply chain (toward the raw milk producer). Failure to maintain such records may result in ineligibility to receive health certifications to the EU.

EU Health Certificates


The applicant shall apply for and obtain the relevant EU Health Certificate from European Union Commission Implementing Regulation [\(EU\) 2020/2235](#) for products containing milk and/or milk products destined to the EU. AMS will issue certificates for the following EU health certificates for which dairy is the final product (including the transit versions):

- Milk-RMP/NT – Chapter 34: Animal health/official certificate for the entry into the Union of dairy products intended for human consumption derived from raw milk or that are not required to undergo a specific risk-mitigating treatment (example: raw milk cheese aged at least 60 days).
- Dairy-Products-PT – Chapter 35: Animal health/official certificate for the entry into the Union of dairy products intended for human consumption that are required to undergo a pasteurization treatment (most dairy products are covered by this certificate).
- Colostrum-BP – Chapter 38: Animal health/official certificate for the entry into the Union of colostrum-based products intended for human consumption.

For the above EU health certificates, the applicant shall ensure the manufacturing plant that puts the product in the final package for export is included on the [Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU.](#) The applicant shall ensure the manufacturing facility identification number code on the dairy product packaging is identical to the facility number on the Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU.”

Please see [Special Considerations for Transit Certificates](#) for unique EU transit certificate requirements.

Additionally, AMS will issue certificates for the following EU composite product health certificates for which dairy is an ingredient:

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- COMP – Chapter 50: Animal health/official certificate for the entry into the Union of not shelf-stable composite products and shelf-stable composite products, containing any quantity of meat products except gelatin, collagen, and highly refined products, and intended for human consumption.
- TRANSIT-COMP – Chapter 52: Animal health certificate for the transit through the union to a third country either by immediate transit or after storage in the union of not shelf-stable composite products and shelf-stable composite products containing any quantity of meat products intended for human consumption.

For the COMP – Chapter 50 health certificate (for composite products containing dairy product ingredients), the applicant shall ensure that any manufacturing plant(s) supplying the dairy ingredient(s) for the final product for export is included on the [Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU](#) and provide the EU listing number.

For the TRANSIT-COMP – Chapter 52 health certificate (for composite products containing dairy product ingredients), the applicant shall ensure that any manufacturing plant(s) supplying the dairy ingredient(s) for the final product for export is either included on the [Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU](#) and provide the EU listing number; or in good standing with the appropriate U.S. regulatory agency. If the manufacturing plant supplying the dairy ingredient is not on the Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU, provide the U.S. identification number such as the Interstate Milk Shipments (IMS) number, USDA number or FDA’s Establishment Identification (FEI) number for each of the dairy ingredient manufacturing plants.

Please see [Special Considerations for Transit Certificates](#) for unique EU transit certificate requirements.

Records Requirements

The applicant shall maintain records demonstrating compliance with EU raw milk requirements to trace back at least one step in the supply chain (toward the processor of dairy ingredients/products or to the raw milk supply) for all dairy products and all applicable dairy ingredients intended for export to the EU. A significant portion of the record keeping requirements may be met by maintaining a Certificates of Conformance (described later in this document) on file for dairy ingredients used within the dairy product or composite product. The applicant will be subject to the AMS Dairy Program EU-EVP to verify compliance with EU requirements.

If AMS is not able to trace records back to the raw milk that demonstrate compliance with the EU SCC and SPC requirements and/or EU regulation 853/2004 indicating milk was sourced from 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, the applicant may be restricted from obtaining future EU health certificates.

Imported Dairy Ingredients

Applicants 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 IMSOC TRACES](#) website-approved dairy facility list for the country of origin, and
- Present a certificate issued by the competent authority of the country of origin certifying, these imported dairy products and ingredients meet all required attestations on the relevant certificate from (EU) 2020/2235, including the requirements of Regulation (EC) No 853/2004.

Milk Supply Traceback and Certificate of Conformance (CoC)

The applicant shall provide the following information, as applicable, to AMS Dairy Program for eligibility of issuance of an EU Health Certificate:

- CoC on company letterhead signed by a responsible official for the applicant (See Exhibit 1.1) or the electronic equivalent.
- CoC from the processor of dairy ingredients/products (See Exhibit 1.2) supplying the products/ingredients the applicant is exporting.
- CoC from milk suppliers (See Exhibit 1.3)

Records containing adequate information to trace back at least one step toward the raw milk source for product(s) covered by the EU Health Certificate are required. This may include production lot identification codes, production dates, bills of lading or any other documentation that provides this information. This information is necessary to verify compliance with (EC) No 853/2004 and the Grade 'A' Pasteurized Milk Ordinance (PMO) or the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements programs during the AMS Dairy Program review of records.


Application Request

The EU Health Certificate can be requested electronically through the [ATLAS platform](#).

The applicant requesting an EU Health Certificate is solely responsible for maintaining the CoC(s) for the dairy products and all dairy ingredients used in the product within the final package for export. The CoC(s) shall provide information necessary to facilitate at least one step trace back toward raw milk production for verification during the AMS Dairy Program review of records.

An applicant who fails to maintain adequate records and CoC(s) to substantiate each request for an EU Health Certificate will be ineligible to obtain future EU Health Certificates. To reestablish eligibility, an AMS Dairy Program review of records will be conducted to determine if adequate records and CoC(s) are maintained to tie the product in the final package for export to raw milk that meets EU requirements through one step trace back (toward raw milk production). This review shall be completed prior to issuance of any certificates to this applicant.

Applicants are advised that production codes, establishment numbers on product containers, shipping

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containers, and seal numbers documented on the EU Health Certificate are required by importing countries or port authorities. The applicant shall ensure the manufacturing facility identification number code on the dairy product packaging is identical to the facility number on the [Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU](#). Applicants should check with the appropriate regulatory authority in the receiving country for any additional requirements.

Retention of Records

The applicant for the EU health certificate, the processor(s) and the milk supplier(s) involved in the production of the product certified for shipment to the EU; must maintain records documenting compliance with EU requirements 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.

Responsibility of Dairy and Composite Product Processors/Manufacturers

To verify compliance with EU regulations AMS Dairy Program will conduct a review of records. The requirements for a processor where the dairy ingredient or composite product requires an EU Health Certificate are:

- A. The processor/manufacturer has on file and available for AMS Dairy Program EU-EVP CoC(s) (see Exhibit 1.3) from their milk and/or dairy ingredient supplier(s) demonstrating the dairy product(s)/dairy ingredient(s) meet Regulation (EC) No 853/2004 for SCC and bacterial SPC requirements.
- B. A dairy or composite product processor’s/manufacturer’s CoC(s) (see Exhibits 1.2 and 1.4) 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 Regulation (EC) No 853/2004 including but not limited to the SCC and bacterial SPC requirements.
 - The dates the dairy product(s)/dairy ingredient(s)/composite products (covered by the CoC) were processed,
 - The location where the documents of compliance can be found,
 - The signature of the individual who is authorized to attest to these statements, and
 - A date when the processor’s/manufacturer’s CoC was signed.
- C. If the dairy product(s)/dairy ingredient(s) is/are imported into the United States from another country, the dairy product(s)/dairy ingredient(s) must have a Health Certificate issued by the sovereign government of the exporting country providing the same assurance as the certificate issued by AMS Dairy Programs EU Health Certificates. This includes dairy product(s)/dairy ingredient(s) imported from the EU or countries maintaining equivalency agreements with the EU. The imported dairy product(s)/ingredients must be from a manufacturing facility identified on the [EU IMSOC TRACES](#) website for the approved dairy facility list for the country origin.

Retention of Records

Records shall be retained to provide:

- A CoC providing adequate information to trace back at least one step toward the raw milk production for products covered by the EU Health Certificate demonstrating milk used to produce those products complies with Regulation (EC) No 853/2004, or
- Any other documentation which can demonstrate the conformance of the SCC and bacterial SPC to the EU requirements and that 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.

Records documenting compliance with EU requirements must be retained 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.

Responsibility of Milk Suppliers

AMS Dairy Program will review the supply chain system used by the milk supplier(s) (for example: cooperative, direct shipper, milk shipper (the entity with farm records), proprietary processor, dairy milk marketer, etc.) supplying milk for processing to verify compliance with SCC and bacterial SPC requirements of Regulation (EC) No 853/2004 and 854/2004. The milk supplier(s) shall have records of individual farms available to confirm that raw milk meeting the SCC and bacterial SPC requirements of the EU is received at the facilities manufacturing dairy products for shipment to the EU. In order to demonstrate compliance with animal health attestations of (EU) 2020/2235 model certificates, 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. Evidence may include farm permits/licenses, farm inspection records, or such other records to verify farm milk production under one of these programs. While a number of different compliance systems devised by the milk supplier(s) may result in compliance with the requirements of Regulation (EC) No 853/2004 and 854/2004, AMS Dairy Program considers the following as minimum requirements:

- A. The milk supplier shall provide a CoC (see exhibit 1.3) that can be used to link products exported to the EU with raw milk meeting SCC and bacterial SPCs of the milk used to produce those products to provide verification of compliance to Regulation (EC) No 853/2004.
- B. To verify compliance with EU requirements (EC) 853/2004 and 854/2004, AMS Dairy Program will conduct a review of records. This review will verify CoCs provided by the milk supplier demonstrate compliance with EU requirements. During the review, a risk-based statistical sampling of the milk supplier's farm records will be reviewed. Farms in the review will consist of only those for which the milk supplier issued a CoC

(farms voluntarily segregated as being non-compliant with EU regulations will not be included in the review).

- C. The milk supplier shall test milk for all farms whose milk or milk products could be incorporated into a product in final package for export to the EU which would require an EU Health Certificate. From each farm, at least two samples per month must be analyzed for bacterial SPC and one sample per month for SCC. Calculation of bacterial SPC means (arithmetic or geometric; hereafter referred to as “mean”) will be based on a rolling two-month time period. Calculation of SCC mean will be based on a rolling three- month time period.
- (1) If a farm’s rolling mean for either the SCC or the bacterial SPC exceeds the maximum EU requirements, the milk supplier must notify AMS Dairy Program and take appropriate measures to bring the farm into compliance.
 - (2) If a farm’s SCC mean or SPC mean exceeds the EU requirements for three consecutive months after the above notification to AMS Dairy Program, as demonstrated in **Table 3** below:

Table 3: Example Dairy Farm Exceeding The SCC Requirements For Shipping To The EU Data For Determining Compliance For Export Of Product To EU

Month	Monthly data for rolling three-month mean for SCC	Result of rolling three- month mean for SCC	Actions
January	Oct, Nov, Dec	> 400,000	Milk ok for export in Jan. Notify AMS.
February	Nov, Dec, Jan	> 400,000	Milk ok for export in Feb. (1st month)
March	Dec, Jan, Feb	> 400,000	Milk ok for export in Mar. (2nd month)
April	Jan, Feb, Mar	> 400,000	Milk NOT ok for export in April. Milk supplier must suspend, segregate, discontinue certification or request derogation. (3rd month)

Table 4: Example dairy farm exceeding the SPC requirements for shipping to the EU Data for determining compliance for export of product to EU

Month	Monthly data for rolling Two Month mean for SPC	Result of rolling Two-month mean for SPC	Actions
January	Nov, Dec	> 100,000	Milk ok for export in Jan. Notify AMS.
February	Dec, Jan	> 100,000	Milk ok for export in Feb. (1st month)
March	Jan, Feb	> 100,000	Milk ok for export in Mar. (2nd month)
April	Feb, Mar	> 100,000	<u>Milk NOT ok for export in April.</u> Milk supplier must suspend, segregate, discontinue certification or request derogation. (3rd month)

The milk supplier must take steps to request a derogation from AMS Dairy Program or exclude the milk from EU certification when they receive the April numbers (that is in early May). AMS Dairy Program will accept derogations as applying retroactively if the milk supplier makes the request within a reasonable time frame.

Additional helpful information related to derogation request can be found at the [EU Dairy Export Certification Programs](#) website.


Through any of the above procedures, the milk supplier will be able to confirm the SCC and bacterial SPC means for milk used to make the product in the final package for export to the EU meets the requirements of the EU.

Retention of Records

Records shall be retained to provide:

- A CoC that can be used to link products exported to the EU with raw milk meeting SCC and bacterial SPCs for the milk used to produce those products to provide verification of compliance to Regulation (EC) No 853/2004.
- 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. Evidence may include farm permits/licenses, farm inspection records, or such other records to verify farm milk production under one of these programs.

Records documenting compliance with EU requirements must be retained 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.

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Special Considerations for Colostrum and Colostrum-based Product Certificates

Colostrum and colostrum-based products are exempt from the SCC and bacterial requirements of Regulation (EC) No 853/2004 and 854/2004. Please note, even though the SCC and bacterial SPC requirements are not required to be met for colostrum and colostrum-based product 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.

For colostrum and colostrum-based products, the applicant shall provide the following information, as applicable, to AMS Dairy Program for eligibility of issuance of an EU Health Certificate:


- CoC on company letterhead signed by a responsible official for the applicant (See Exhibit 2.1) or the electronic equivalent.
- CoC from the processor of dairy ingredients/products (See Exhibit 2.2) supplying the products/ingredients the applicant is exporting.
- CoC from colostrum suppliers (See Exhibit 2.3)

Special Considerations for EU Transit Certificates

Shipments transiting the EU to third countries 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 of Regulation (EC) No 853/2004 and 854/2004 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.

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 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.

Additionally, while the manufacturing plant(s) supplying the dairy ingredient(s) for the final product are not specifically required to be on the Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU, the plant(s) must be in good regulatory standing with a U.S. regulatory agency. This can be demonstrated/verified by the manufacturing plant(s) appearing on one of the following lists:

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- Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU with an EU approval number
- IMS list with an IMS identification number
- USDA Plant List with a USDA identification number or
- AMS Export Eligible Producing facilities list with a FEI number

The identification number from the list utilized will be printed on the certificate. Exporters should ensure the plant identification number on the product labeling matches the identification number from the list utilized as border inspection post personnel often review this information for consistency.

Special Considerations for Great Britain Certificates

On January 1, 2021, the United Kingdom (UK) completed its departure from the European Union (EU). The UK’s full name is the United Kingdom of Great Britain (GB) and Northern Ireland (NI), where GB includes the devolved nations of England, Wales and Scotland and their islands. For the purposes of international trade, the Isle of Man and the Channel Islands are in the same Sanitary and Phytosanitary (SPS) zone as GB; however, NI remains in the same SPS zone as the EU.

Dairy exports destined to GB (including England, Wales, Scotland, the Isle of Man and the Channel Islands) will need to utilize the new GB dairy and composite product certificates. While exports destined for Northern Ireland (NI) should utilize the EU dairy and composite product certificates.

Both the GB and EU certificates are available in the AMS [Agriculture Trade Licensing & Attestation Solution \(ATLAS\)](#) web-based software.

For dairy products or composite products destined for Great Britain, the manufacturing facility(s) responsible for packaging the product for export, or if a dairy ingredient is used in the manufacture of a composite product, the dairy/dairy ingredient manufacturing facility must be listed on the [“List of establishments eligible to export animal products to the UK.”](#)

Special Considerations for Turkey Certificates

For dairy products destined for Turkey, the manufacturing facility(s) responsible for packaging the dairy product is not required to be on the Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU, however, the plant(s) must be in good regulatory standing with a U.S. regulatory agency. This can be demonstrated/verified by the manufacturing facility(s) appearing on one of the following lists:

- Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products” approved for export to the EU with an EU approval number
- IMS list with an IMS identification number
- USDA Plant List with a USDA identification number
- AMS Export Eligible Producing facilities list with a FEI number

Appendix A.

Calculation of Rolling Geometric Mean (G.M.)

The EU uses a rolling geometric mean to determine compliance with the SCC and bacterial SPC requirements of Regulation (EC) No. 853/2004. AMS Dairy Programs certification will recognize rolling geometric means of results from samples of raw milk from individual farms taken once per month over a three-month period for SCC and twice per month over a two-month period for bacterial SPCs.

(Note many calculators have a key labeled “X1/y” which can be used to calculate the geometric mean. “X” equals the result from B below and “y” equals 3. Some computer spreadsheet software programs have a geometric mean calculation function.)

SCC Example Calculations:

- A. Determine the farm’s SCC for each of the prior two months and the current month (3 months).
- B. Multiply the three-monthly results.
- C. Compute the cube root of the result from B to obtain the geometric mean. Round the result to the nearest thousand.

<u>Monthly SCC Count</u>	<u>Geometric Mean</u>
Month #1 – 400,000	
Month #2 – 350,000	
Month #3 – 300,000	348,000 for Month #3
Month #4 – 600,000	398,000 for Month #4
Month #5 – 400,000	416,000 for Month #5
Month #6 – 250,000	391,000 for Month #6

$$G.M. (Somatic Cell Count) = \sqrt[3]{Month1 \times Month2 \times Month3}$$

Bacterial SPC Example Calculations:


(Note many calculators have a key labeled “X1/y” which can be used to calculate the geometric mean. “X” equals the result from B below and “y” equals 4. Some computer spreadsheet software programs have a geometric mean calculation function.)

- A. Determine the farm’s bacterial SPC average from samples taken from the farm for two separate randomly selected days per month. Obtain two bacterial counts from the current month and two from the prior month for a total of four.
- B. Multiply the four counts.
- C. Compute the fourth root of the result from B to obtain the geometric mean. Round the result to the nearest thousand.

<u>Bacterial SPC Average Values</u>	<u>Geometric Mean</u>
Month #1 – Sampling #1 (Month1 ₁) – 45,000	
Month #1 – Sampling #2 (Month1 ₂) – 25,000	
Month #2 – Sampling #1 (Month2 ₁) – 20,000	
Month #2 – Sampling #2 (Month2 ₂) – 15,000	24,000 for Month #2
Month #3 – Sampling #1 (Month3 ₁) – 70,000	
Month #3 – Sampling #2 (Month3 ₂) – 50,000	32,000 for Month #3

$$G. M. (Bact.) = \sqrt[4]{Month1_1 \times Month 1_2 \times Month2_1 \times Month2_2}$$

G.M = 24,100 for Month #2

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Appendix B.

Application for Requesting EU Health Certificates

Applicants must request the new EU Health certificates through the [ATLAS platform](#) and provide an appropriate CoC (copies of blank documents are included below). Important Note: The EU has a strict requirement that all EU health certificates be issued prior to a shipment's departure date. Be sure to request EU certificates to allow time for processing/issuance prior to the departure date.

Applicants are subject to annual EU-EVP Reviews by AMS Dairy Program to verify that information provided on the request and CoCs are valid. By submitting your request, you are certifying you have documentation to verify the product meets the EU requirements and all information on the EU Health Certificate. Applicants will be billed for time for the EU-EVP Reviews and subsequent follow up Reviews.

Certificates are processed by the [ATLAS](#) system in the order they are received. Training for the ATLAS system is available at: [Training on the new Agriculture Trade Licensing & Attestation Solution System | Agricultural Marketing Service \(usda.gov\)](#)

The applicant shall maintain a copy of the appropriate CoC for each request. The statement must be on company letterhead, contain a legible address, phone number, required production information, and be signed by a responsible company official.

- The exporter cannot make changes to the certificate. No alterations can be made to the certificate after endorsement by AMS.
- EU Health Certificates are billed at the rate [currently published](#) in the [Federal Register](#) by AMS. Certified copies and additional services, such as faxes, PDF copies, or special handling will result in additional charges.
- Allow at least 5 business days for processing.

Exhibit 1.1

Certificate of Conformance for Applicants

The Certificate of Conformance shall be provided on company letterhead that includes company name, physical address, email address, contact printed name and phone number. This Certificate of Conformance shall be signed and dated for each shipment of product; “blanket certificates” are not acceptable.

Certificate of Conformance

Applicant for European Union Health Certificate:

I hereby certify that all of the dairy products and/or dairy ingredients used for the production of the products included in the attached request for certification were produced from raw milk meeting the somatic cell count (SCC) (400,000 per ml.) and bacterial standard plate count (SPC) (100,000 per ml.) requirements of Regulation (EC) No 853/2004 Annex III, Section IX, Chapter I, III: Criteria for Raw Milk and Colostrum and that 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.

The signer of this Certificate of Conformance acknowledges responsibility for maintaining adequate records to trace one step in the supply chain (toward the raw milk producer). A Certificate of Conformance is required for all dairy products or ingredients used in the products presented for certification. Failure to maintain such records will cause the applicant ineligibility to receive certifications to the European Union.

Signature

Date

Printed Name

Title

Email Address

Dairy product name, lot numbers and manufacturing dates covered by this certificate of conformance are listed below:

Product Name	Lot numbers	Manufacturing Dates

Exhibit 1.2

Certificate of Conformance for Composite Product Processor, Dairy Processor, or Manufacturer

The Certificate of Conformance shall be provided on company letterhead that includes company name, physical address, email address, contact name and phone number. This Certificate of Conformance shall be signed and dated for each shipment of product; “blanket certificates” are not acceptable.

Certificate of Conformance

Processors of Composite Products and/or Dairy Ingredients:

I hereby certify that all of the dairy products and/or dairy ingredients used for the production of the products included in the attached consignment were produced from raw milk meeting the somatic cell count (SCC) (400,000 per ml.) and bacterial standard plate count (SPC) (100,000 per ml.) requirements of Regulation (EC) No 853/2004 Annex III, Section IX, Chapter I, III: Criteria for Raw Milk and Colostrum and that 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.

The signer of this Certificate of Conformance acknowledges responsibility for maintaining adequate records to trace one step in the supply chain (toward the raw milk producer). A Certificate of Conformance is required for all dairy products or ingredients used in the products covered by this certificate. Failure to maintain such records will cause the applicant ineligibility to receive certifications to the European Union.

Signature

Date

Printed Name

Title

Email Address

Dairy Product Name, Lot Numbers and Manufacturing Dates Covered By This Certificate Of Conformance Are Listed Below:

Product Name	Lot numbers	Manufacturing Dates

Exhibit 1.3

Certificate of Conformance for Milk Suppliers:

The Certificate of Conformance shall be provided on company letterhead that includes company name, physical address, email address, contact name and phone number. This Certificate of Conformance must be provided by suppliers with each shipment of milk used in product manufactured for shipment to the EU.

Certificate of Conformance

Milk Supplier:

I hereby certify that the raw milk provided to your facility were produced from farms meeting the somatic cell count (400,000 per ml.) and bacterial standard plate count (100,000 per ml.) requirements of the Regulation(EC) No 853/2004 Annex III, Section IX, Chapter I, III: Criteria for Raw Milk and Colostrum and that 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.

_____	_____
Signature	Date
_____	_____
Printed Name	Title

Email Address	

Period covered by Certificate of Conformance, not to exceed one month:

Beginning Date	End Date

Exhibit 1.4

Certificate of Conformance Composite Products

The Certificate of Conformance shall be provided on company letterhead that includes company name, physical address, email address, contact name and phone number. This Certificate of Conformance shall be signed and dated for each shipment of product; “blanket certificates” are not acceptable.

Certificate of Conformance

Processors of Composite Products:

I hereby certify that all of the dairy products and/or dairy ingredients used for the production of the products included in the attached consignment were produced from raw milk meeting the somatic cell count (400,000 per ml.) and bacterial standard plate count (100,000 per ml.) requirements of Regulation (EC) No 853/2004 Annex III, Section IX, Chapter I, III: Criteria for Raw Milk and Colostrum and that 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.

The signer of this Certificate of Conformance acknowledges responsibility for maintaining adequate records to trace one step in the supply chain (toward the raw milk producer). A Certificate of Conformance is required for all dairy products or ingredients used in the products covered by this certificate. Failure to maintain such records will cause the applicant ineligibility to receive certifications to the European Union.

Signature

Date

Printed Name

Title

Email Address

Dairy product name, lot numbers and manufacturing dates covered by this certificate of conformance are listed below:

Product Name	Lot numbers	Manufacturing Dates

Exhibit 2.1

Certificate of Conformance for Applicants for Colostrum-Based Products/or Ingredients

The Certificate of Conformance shall be provided on company letterhead that includes company name, physical address, email address, contact printed name and phone number. This Certificate of Conformance shall be signed and dated for each shipment of product; “blanket certificates” are not acceptable.

Certificate of Conformance for colostrum-based products/or colostrum-based ingredients

Applicant for European Union Health Certificate-

I hereby certify that all the colostrum-based products/or colostrum-based ingredients used for the production of the products included in the attached request for certification were supplied by colostrum from 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.

The signer of this Certificate of Conformance acknowledges responsibility for maintaining adequate records to trace one step in the supply chain (toward the colostrum producer). A Certificate of Conformance is required for all colostrum products or colostrum ingredients used in the products presented for certification. Failure to maintain such records will cause the applicant ineligibility to receive certifications to the European Union.

Signature

Date

Printed Name

Title

Email Address

Dairy product name, lot numbers and manufacturing dates covered by this certificate of conformance are listed below:

Product Name	Lot numbers	Manufacturing Dates

Exhibit 2.2

Certificate of Conformance for Colostrum Based-Products/or Ingredients Processor or Manufacturer

The Certificate of Conformance shall be provided on company letterhead that includes company name, physical address, email address, contact printed name and phone number. This Certificate of Conformance shall be signed and dated for each shipment of product; “blanket certificates” are not acceptable.

Certificate of Conformance for Colostrum-Based Products/or Colostrum-Based Ingredients

Processor or Manufacturer for Colostrum-based:

I hereby certify that all the colostrum-based products/or colostrum-based ingredients used for the production of the products included in the attached consignment were supplied by colostrum from 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.

The signer of this Certificate of Conformance acknowledges responsibility for maintaining adequate records to trace one step in the supply chain (toward the colostrum producer). A Certificate of Conformance is required for all colostrum products or colostrum ingredients used in the products covered by this certificate. Failure to maintain such records will cause the applicant ineligibility to receive certifications to the European Union.

Signature

Date

Printed Name

Title

Email Address

Dairy product name, lot numbers and manufacturing dates covered by this certificate of conformance are listed below:

Product Name	Lot numbers	Manufacturing Dates

Exhibit 2.3

Certificate of Conformance for Colostrum Suppliers

The Certificate of Conformance shall be provided on company letterhead that includes company name, physical address, email address, contact printed name and phone number. This Certificate of Conformance shall be signed and dated for each shipment of Colostrum/or Colostrum-based ingredients.

Certificate of Conformance for Supplier of Colostrum /or Colostrum-Based Ingredients

Colostrum Supplier:

I hereby certify that all the colostrum/or colostrum-based ingredients were produced by colostrum from 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.

Signature

Date

Printed Name

Title

Email Address

Period covered by Certificate of Conformance, not to exceed one month:

Beginning Date:	End Date