AMS DAIRY PROGRAM
DAIRY GRADING BRANCH

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

Eligibility for USDA AMS Dairy Export Certificates to the European Union, United Kingdom, and Turkey

Dairy Grading and Standardization Division

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1. Introduction:

These instructions establish the responsibilities and procedures to maintain eligibility for obtaining European Union (EU) Export Certificates (hereafter referred to as "EU Export Certificate"). The program outlined in these instructions shall be used to demonstrate compliance with Regulation (EU) No 853/2004, Implementing Regulation (EU) 2019/627, Regulation (EU) 2016/429, Commission Delegated Regulation 2020/692, Implementing Regulation (EU) 2022/1255, Commission Implementing Regulation (EU) 2020/2235, and Regulation (EU) 2017/625. These and other European Union (EU) regulations in this document outline the requirements to export dairy products from the United States to the EU.

At the time of this issuance, twenty-seven (27) importing Member Countries of the EU are identified in **Table 1** below.

Table 1: European Union Member Countries

Austria	Belgium	Bulgaria	Croatia
Cyprus	Czechia	Denmark	Estonia
Finland	France	Germany	Greece
Hungry	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 Export Certificates:

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

Iceland	Liechtenstein	Norway	Switzerland

The requirements outlined in this document also demonstrate raw milk compliance with Somatic Cell Count (SCC) requirements and bacterial Standard Plate Count (SPC) requirements for United Kingdom and Turkey which are similar to EU requirements.

2. Audience:

This document is intended for industry stakeholders involved in all stages of the supply chain of exported dairy products, dairy ingredients, and/or composite products containing dairy ingredients to the European Union, United Kingdom, and Turkey and utilize USDA AMS EU Export Certificates. The Antimicrobial Resistance requirement is only applicable to dairy products and ingredients intended for human consumption entering the European Union.

3. Scope and Products Covered:

The requirement to provide an EU Export 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 the product's standard of identity that *milk or dairy products originate from cow, buffalo, sheep, goat or "females of other species belonging to herds"*, will require an EU Export Certificate and are covered under this program.

Composite products containing dairy ingredients are also covered under this program. The EU defines a *composite product as a non-shelf stable 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, collagen/gelatine products, processed honey products, and meat products. If a composite product contains a dairy product ingredient, this export verification

program is applicable.

Note: Export verification programs for other animal origin ingredients (egg, fishery, meat products, and/or gelatine or collagen derived from ruminant bones) may also be applicable and additional certificates may be required at port arrival.

4. Definitions:

- **Agricultural Marketing Service (AMS):** An agency within the U.S. Department of Agriculture (USDA) that administers programs to facilitate the marketing of U.S. agricultural products domestically and internationally. AMS is the recognized certification authority for products described in this document and is where the Dairy Program's Grading Branch resides.
- **Animal and Plant Health Inspection Service (APHIS):** Competent authority for animal health in the U.S.
- **Applicant (exporter or consignor):** An entity submitting a request for an EU Export Certificate; an Applicant could be a manufacturer, broker or other entity exporting goods
- **Audit**: An audit, also referred to as a record review, is a formal examination of an organization's records
- **Colostrum:** The EU and United Kingdom defines colostrum as the fluid secreted by the mammary glands of milk producing animals up to three to five days post parturition that is rich in antibodies and minerals, and precedes the production of raw milk (Turkey certificates are not issued for Colostrum)
- **Colostrum-based products:** The EU and United Kingdom define colostrum-based products as processed products resulting from the processing of colostrum or from the further processing of such processed products (**Note:** Turkey certificates are not issued for Colostrum-based products)
- **Competent Authority:** A government appointed body responsible for enforcing laws and regulations. An agency with legal power to make decisions and enforce laws in a specific area for public policy
- **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)
- **Composite product**: a food containing both processed products of animal origin and products of plant origin
- **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.
- **Dairy Product**: milk or dairy products originate from milk from cow, buffalo, sheep, goat or "females of other species belonging to herds"
- **Derogation**: A submission to AMS Dairy Program for a farm's Somatic Cell Count (SCC) or bacterial Standard Plate Count (SPC) rolling geometric mean that exceeds the EU requirements for three consecutive months following a notification and allowing the farm to continue exporting to the EU for a 12-month period
- **European Union (EU):** consists of the 27 member states identified in Table 1. The European Commission is the EU's main executive body and implements requirements that serve as the basis of this EVP
- **Food and Drug Administration (FDA)**: Competent authority for public health for dairy and other products covered within this document. FDA provides for USDA AMS to be a delegated certifying official (MOU 225-20-017)
- **United Kingdom (GB)**: United Kingdom, while a separate entity from the European Union, follows similar requirements as the European Union except for the antimicrobial resistance requirements. The two-letter country code for United Kingdom is GB.
- **Milk Supplier**: The supplier of milk used in the manufacture of the dairy product(s). For example: cooperative, direct shipper, milk shipper (the entity with farm records), proprietary processor,

dairy milk marketer, etc.

- **Notification**: A submission to AMS Dairy Program for a farm's Somatic Cell Count (SCC) or bacterial Standard Plate Count (SPC) rolling geometric mean that exceeds the EU requirements for the first time
- **Raw Milk**: is defined in Regulation (EC) 853/2004 as milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40°C or undergone any treatment that has an equivalent effect
- **Renewal Derogation**: A submission to AMS Dairy Program for a farm's Somatic Cell Count (SCC) or bacterial Standard Plate Count (SPC) rolling geometric mean that exceeds an EU requirement following a derogation submission, valid for 12-months
- **Third Country Establishments:** Dairy product manufacturing facilities originating in another country, not the United States. When dairy products are imported from another country and further processed in the United States, the manufacturing company in the other country must be listed on the EU IMSOC List.
- **Turkey:** Turkey, while a separate entity from the European Union, follows similar requirements as the European Union except for the antimicrobial resistance requirements
- **USDA Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements:** USDA provided document for processing milk for manufacturing

5. Dairy Establishment Listing Requirement:

For many products of animal origin, including milk and dairy products, the EU only accepts imports originating from third country establishments that appear on the EU's lists of third country establishments. The EU maintains the lists of approved establishments based on submissions from the competent authorities of exporting countries. The 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 U.S. dairy manufacturers is identified by the EU as the "Approved Establishments" list. It includes "Raw milk, dairy products, colostrum and colostrum-based products" list 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 link in the References.

Note: Relevant establishments must be officially listed on the EU's lists of third country establishments by the EU for products to be eligible for entry. FDA sends the IMSOC approved suppler list/TRACES List updates to the EU on a quarterly basis. The most current version of the list is available online and should be referenced as the most up to date list. Please consult the official lists posted on the EU Integrated Management System for Official Controls/Trade Control and Expert System (IMSOC/TRACES) to ensure the relevant establishment is listed by the EU before attempting to request an EU Export Certificate.

Dairy plants supplying dairy product(s) or dairy ingredient(s) to an EU export certificate Applicant, but do not ship dairy product directly to the EU, are required to be listed if their product is used as an ingredient in a dairy or dairy composite product exported to the EU. Dairy plants supplying dairy ingredients for further processing in the U.S. or other third countries (i.e., New Zealand) must be listed on the EU IMSOC approved suppliers list. Also, dairy products or ingredients manufactured in another country must be accompanied by an import certificate and the manufacturer must be listed on the EU IMSOC list under the country of origin.

6. EU Regulations for Dairy Products:

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, Commission Implementing Regulation (EU) 2020/2235, Commission Implementing Regulation (EU) 2022/1255, and Commission Delegated Regulation 2023/905. These comprehensive regulations address many issues related 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 (**Note:** These differences are not applicable for colostrum):

- The EU SCC and bacterial SPC requirements apply at the farm level.
- The method for calculating SCC and bacterial SPC averages is a 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 Somatic Cell Count in raw cow's milk for the production of heat-treated milk, milk products and other milk-based products is 400,000/ml.
  - The maximum bacterial Standard Plate Count for raw cow's milk for the production of heat-treated milk, milk products and other milk-based products is 100,000 CFU/ml.

Grade 'A' cow's milk and Milk for Manufacturing Grade cow's milk in the U.S. are regulated at maximum SCC of 750,000/ml. Grade 'A' milk in the U.S. is regulated at a bacterial SPC of 100,000 CFU/ml or less. The recommended regulatory bacterial SPC for Milk for Manufacturing Grade cow's milk in the U.S. is 500,000/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 Manufacturing Grade milk for SCC and only Manufacturing Grade 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.

The Applicant for the EU export 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 EU SCC and bacterial SPC compliance as well as 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 "USDA Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements" or comparable state regulations, for a minimum of 12 months after the date of shipment or since the last AMS EU-EVP Audit, whichever is longer. Records retention is not required beyond three years. These records must be available for review during an AMS EU-EVP Audit.

As indicated in, Commission Implementing Regulation (EU) 2024/399, which was amended by Commission Implementing Regulation 2025/636, consignments covered by export certificates destined for the European Union, signed on or after 3 September 2026, must provide documentation and demonstrate the source animals from which raw milk was obtained have not been administered any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022.

Note: EU 2022/1255 does not apply to composite certificates. The list of prohibited antimicrobials can be found in Appendix D of this document.

7. EU Application Process:

Applicants must request EU Export Certificates through the ATLAS platform and provide its Certificate of Conformance (CoC), as requested (example documents are included in Appendix B), as well as maintain

its dairy supplier CoC to be reviewed during an AMS audit. If requesting an EU Chapter 50 or 52 composite export certificate, the CoC for all dairy ingredient manufacturers must be attached in the ATLAS application. This requirement allows Dairy Program Auditors to review these documents during the pre-audit phase of the EU-EVP audit process and will minimize the number of documents requested for review during the actual audit process.

Important Note: The EU has a strict requirement that all EU Export Certificates be issued prior to a shipment's departure date from the United States. Be sure to request EU certificates to allow time for processing and issuance prior to the shipment's departure date.

Applicants are subject to European Union Export Verification Program (EU-EVP) audit(s) conducted by AMS Dairy Program. The purpose of each audit is to verify attestations and all information noted on the export certificate(s); establish that CoCs are available and valid; and ensure all other EU requirements are met. By submitting your application, you are certifying you have documentation to verify the product(s) subject to export to the EU meet all EU Export certificate and country requirements. Applicants will be billed for time spent conducting the EU-EVP Audit and subsequent follow up Audit(s) will be performed and billed according to the billing rate listed in the Federal Register Rates Charged for AMS Services. All export certificates issued to the European Union, United Kingdom, and Turkey are subject to review.

The Applicant must include a copy of the appropriate CoC(s) for each application (see Exhibit 1.1 for dairy products and Exhibit 2.1 for colostrum products). 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 Applicant cannot make changes to the export certificate after it is endorsed by USDA AMS. In a limited number of circumstances, a replacement export certificate (amendment) may be requested from USDA AMS. Article 6 Commission Implementing Regulation (EU) 2020/2235 states that competent authorities shall only issue replacement certificates for consignments of animals and goods intended for human consumption in the case of administrative errors in the initial certificate or where the initial certificate has been damaged or lost. Competent authorities may not modify information in the initial certificate concerning the identification of the consignment, its traceability, and the guarantees provided for in the initial certificate.

EU Export Certificates are billed at the rate currently published on the Service Fees, Agricultural Marketing Service website. Certified copies and additional services, such as faxes, PDF copies, or special handling will result in additional charges. Certificates are processed by the ATLAS system in order they are received. Please allow at least five business days for certificate processing. Training for the ATLAS system is available in the Reference Section of this document.

8. EU Export Certificate types:

The Applicant shall apply for and obtain the relevant EU Export 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 EU Export Certificates for which dairy is in the final product. In instances when milk and/or milk products are in transit through the EU to another country, AMS will issue an EU Transit Certificate(s). Specific transit certificates for Chapter 34, 35, and 38 are identified below.

- **Milk-RMP/NT – Chapter 34**: Animal health/official certificate for the entry into the EU of dairy products intended for human consumption derived from raw milk or dairy products therefrom, or both, 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 EU 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 EU of colostrum-based products intended for human consumption.

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

- **COMP – Chapter 50:** Model animal health/official certificate for the entry into the EU of non-shelf-stable composite products intended for human consumption and shelf-stable composite products intended for human consumption and containing any quantity of meat products except Gelatine not derived from ruminant bones, collagen not derived from ruminant bones and highly refined product, and any quantity of colostrum-based products.
- **TRANSIT-COMP – Chapter 52:** Model animal health certificate for the transit through the EU to a third country either by immediate transit or after storage in the EU of non-shelf-stable composite products intended for human consumption and shelf-stable composite products intended for human consumption and containing any quantity of meat products except gelatine, collagen and highly refined products, and any quantity of colostrum-based products.

9. Applicant Responsibility:

Applicants must request an EU export certificate through the ATLAS platform and agree to the attestation statements presented prior to application submission.

Applicants requesting Chapter 34, 35, and 38, EU Export Certificates shall ensure the manufacturing plant places the product in the final package for export. All plants contributing dairy ingredients to the dairy or composite product must be included on the Approved Establishments list for the U.S. for “Raw milk, dairy products, colostrum and colostrum-based products”. To comply with the EU's identification mark requirements in Section I of Annex II of Regulation (EC) No 853/2004, the Applicant shall ensure the manufacturing facility identification number listed 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”. The package must also identify the name of the country in which the establishment is located either written out in full or with the ISO code "US".

9.1 Pre-requisites:

The following statements are required in the ATLAS application and must be approved by the Applicant:

- 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 AMS Dairy Program Payments.
- I certify that the entity that I am submitting an application for is approved to export items to the country specified.
- I certify that all of the dairy products and/or dairy ingredients used for the production of the final products included in the application were produced from:
    - Raw milk that meets the SCC (400,000 per ml.) and bacterial SPC (100,000 CFU 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(s) 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 the ineligibility to receive export certifications to the EU.
- I acknowledge by clicking this box the information is factual and accurate.
- I acknowledge this certificate may be verified through a records review conducted by AMS Dairy Program. Suppliers may be subject to a supply chain traceability review, where applicable. Any associated costs for scheduling and conducting such reviews are the responsibility of the reviewed party.

On EU Chapter 34, 35 and 38 certificate types, the Applicant will also be required to approve the statement below as well as attest to the pre-requisites above.

I certify that as applicable to consignments covered by export certificates destined for the European Union, signed on or after 3 September 2026, the source animals from which raw milk was obtained have not been administered any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022. **Note:** Applies only to dairy certificates; not to composite certificates.

9.2 Applicant Certificate of Conformances:

The Applicant requesting an EU Export Certificate is solely responsible for maintaining the Applicant CoC(s) confirming, as the last step in the supply chain, the dairy product or ingredient meets EU regulations. The Applicant is also 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 EU EVP Audit.

During the application process, the Applicant CoC must be included in the application. The Applicant CoC must be lot specific and traceable through the supply chain. The statement must be on the company letterhead, contain a legible manufacturing facility address, phone number, required production information, and be signed by a responsible company official. If the Applicant does not further manufacture the dairy product or ingredient and does not assign the product their own lot number, the manufacturer lot number may be referenced.

Applicants are advised that production codes, establishment numbers, shipping container numbers, and seal numbers (as applicable) must be accurately documented on the EU Export Certificate and are required by the importing country port authorities. Applicants should check with the appropriate regulatory authority in the receiving country for any additional requirements.

The Applicant CoC must be presented with the EU certification application. The applicant must also maintain dairy supplier CoC's to be reviewed during an AMS EU-EVP audit. If requesting an EU Chapter 50 or 52 composite export certificate, the CoC for all dairy ingredient manufacturers must be attached in the EU certificate application.

9.3 Applicant Records:

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 CoC on file for dairy ingredients used within the dairy product or composite product. The Applicant will be subject to the AMS EU-EVP audit to verify compliance with EU requirements.

If AMS is not able to trace records back to the raw milk to demonstrate compliance with the EU SCC

and bacterial SPC requirements and/or EU Regulation (EC) 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 or comparable state regulations, or compliance with the EU's prohibited antimicrobials requirement, the Applicant may be restricted from obtaining future EU Export Certificates.

The Applicant for the EU Export 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 AMS EU-EVP Audit, whichever is longer. Retention of records shall not be required beyond three years. These records must be available prior to or during an AMS EU-EVP Audit.

An Applicant who fails to maintain adequate records and CoC(s) to substantiate each application for an EU Export Certificate could be ineligible to obtain future EU Export Certificates. To re-establish eligibility, an AMS Dairy Program Auditor will conduct an AMS EU-EVP Audit to determine if adequate records and CoC(s) are maintained. This audit shall be completed prior to the issuance of any EU certificates to this Applicant.

10. Dairy Product Processors/Manufacturers Responsibility:

Dairy product processors/manufacturers must have records available and provide factual supporting documentation to the Applicant, when an Applicant is submitting an EU Export Certificate application. Manufacturers must provide the location of manufacture of the dairy product, dairy product batch numbers, maintain a signed CoC, to demonstrate the manufacturer's location, and, as applicable, maintain signed CoCs for dairy ingredients used in the dairy product.

If dairy ingredients are used in the dairy product that was exported, and the dairy ingredients were manufactured in another U.S. plant, the dairy ingredients' manufacturers must provide a CoC for their products and the manufacturer of the final product must maintain their suppliers' CoCs for review during the AMS EU-EVP Audit. If raw milk is used as an ingredient, the dairy product or ingredient manufacturer must also maintain the raw milk supplier's CoC.

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 an import certificate issued by the sovereign government of the exporting country demonstrating adherence to European Union requirements and attestations on the EU Export Certificate(s) issued by AMS Dairy Program. 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 website for the approved dairy facility list for the country origin.

It is the responsibility of each dairy processor and manufacturer exporting or supplying raw milk and dairy ingredients to those companies exporting to the EU to ensure the manufacturing plant is included on the Approved Establishments list of the U.S. for "Raw milk, dairy products, colostrum and colostrum-based products" approved for export to the EU.

Dairy product processors and dairy ingredient manufacturers are subject to an AMS EU-EVP Audit to ensure the raw milk used during the process meets EU regulations.

10.1 Manufacturer Certificate of Conformances:

To verify compliance with EU regulations, AMS Dairy Program will conduct a documentation audit, including a review of Certificate of Conformances (CoCs). The CoCs must be on the company letterhead, contain a legible manufacturer/processor facility address, phone number, required

production information, and be signed by a responsible company official. The requirements for a manufacturer/processor where the dairy ingredient or composite product requires an EU Export Certificate are:

- The manufacturer/processor has on file and available for AMS Dairy Program, 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.
- The raw milk was supplied by credentialed (permitted/licensed) farms regulated either under the requirements of the Grade 'A' Pasteurized Milk Ordinance (PMO) or "USDA Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements".
- For non-composite dairy products only, manufacturers/processors must also have on file documentation confirming the milk manufacturer/processor has implemented protocols ensuring the raw milk is sourced from farms that have not administrated any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022, as applicable for consignments certified for entering the European Union from 3 September 2026.

The manufacturer/processor CoC must be lot specific and traceable through the supply chain.

The manufacturer/processor shall provide the following information, as applicable, to AMS Dairy Program for eligibility of issuance of an EU Export 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 the composite product manufacturer (see Exhibit 1.4) supplying the composite product the Applicant is exporting.
- CoC from milk suppliers (See Exhibit 1.3).

10.2 Manufacturer Records:

Retention of records shall not be required beyond three years. These records must be available during an AMS EU-EVP Audit. A CoC providing adequate information to trace back at least one step toward the raw milk production for products covered by the EU Export Certificate demonstrating milk used to produce those products comply with Regulation (EC) No 853/2004.

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 or comparable state regulations.

For non-composite dairy products only: Documentation confirming the milk processor has implemented protocols ensuring the raw milk is sourced from farms that have not administrated any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022, as applicable for consignments certified for entering the European Union from 3 September 2026.

11. Milk Suppliers Responsibility:

AMS Dairy Program will review the supply chain system used by the milk supplier(s) supplying milk for processing to verify compliance with SCC and bacterial SPC requirements of Regulation 853/2004. The milk supplier(s) shall have rolling geometric mean records of individual farms available to confirm the 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.

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 other records to verify farm milk production under one of these programs.

AMS will also review the processor/manufacturer/milk supplier's documentation of protocols implemented to ensure that raw milk is sourced from farms that have not administrated any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022, as applicable for consignments certified for entering the European Union from 3 September 2026.

11.1 Raw Milk Supplier Certificate of Conformances & Affidavit:

A raw milk supplier CoC should be available to the dairy product manufacturer and maintained with the raw milk supplier. A raw milk CoC allows for a 1-month blanket to be listed on the certificate. The statement must also be on company letterhead, contain the representing facility address, phone number, required production information, and be signed by a responsible company official. A CoC can be used to link products exported to the EU with raw milk meeting SCC and bacterial SPC for the milk used to produce those products to provide verification of compliance to Regulation (EC) No 853/2004.

For consignments certified for entering the EU from 3 September 2026, all raw milk suppliers must maintain written documentation demonstrating they have informed their farms that the antimicrobials listed in Appendix D, from EU 2022/1255, were not administered to dairy animals whose product was exported to the EU. The Affidavit located in Appendix C shall be completed annually by the party responsible for representing the farms. Raw milk suppliers are responsible for issuing notifications to farms annually. An example of the documentation provided to the farms must be available during an AMS EU-EVP Audit.

Note: If a dairy product or dairy ingredient was manufactured prior to 3 September 2026, the dairy product or dairy ingredient is still required to be from animals not treated with the antimicrobials listed on EU 2022/1255. A raw milk supplier CoC shall be made available to the dairy product manufacturer.

The raw milk supplier shall provide the following information, as applicable, to AMS Dairy Program for eligibility of issuance of an EU Export Certificate:

- CoC from milk suppliers (See Exhibit 1.3)
- CoC for milk suppliers if milk is purchased (See Exhibit 1.3)
- Antimicrobial Affidavit (See Appendix C)

11.2 Raw Milk Supplier Records:

While different compliance systems devised by the milk supplier(s) may result in compliance with the requirements of Regulation 853/2004, AMS Dairy Program considers the following as minimum documentation 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.

B. To verify compliance with EU requirement 853/2004, AMS Dairy Program will conduct

an audit of records. The audit will verify CoCs provided by the milk supplier demonstrate compliance with EU requirements. During the audit, a risk-based statistical sampling of the milk supplier's farm records will be reviewed. Farms in the audit 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 the final package for export to the EU which would require an EU Export 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 period. Calculation of the 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 bacterial SPC mean exceeds the EU requirements for three consecutive months after the above notification, the raw milk supplier must either submit a request to AMS Dairy Program for a derogation or remove the farm's milk from European Union product production.

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" or comparable state regulations. Evidence may include farm permits/licenses, farm inspection records, or other records to verify farm milk production under one of these programs.

Note: If a farm permit/license number is provided without a copy of the certification, the expiration date must be provided, and the permit/license number must also be found on the state or county inspection website.

Records supporting EU production, CoCs, and for milk suppliers, the antimicrobial affidavit, documenting compliance with EU requirements must be retained for a minimum of 12 months after the date of shipment or since the last AMS EU-EVP Audit, whichever is longer. Retention of records shall not be required beyond three years. These records must be available during an AMS EU-EVP Audit.

11.3 Notifications and Derogations

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. If the raw milk rolling geometric mean does not meet EU Requirement of <400,000/ml for SCC and/or <100,000 CFU/ml for bacterial SPC, the non-compliant milk must either be segregated from EU production, or the raw milk supplier must notify AMS Dairy Program.

Appendix A demonstrates how to calculate rolling geometric mean results for both SCC and bacterial SPC. If a farm has a monthly rolling geometric mean result above the EU regulation requirements, the

first high result is a notification and must be submitted to AMS Dairy Program at no cost. If the consecutive 3-months after the notification are still above the EU regulation requirement, a derogation must be submitted, and derogation fees are applicable. A derogation is valid for 12 months after the derogation month is submitted and the farm's milk will be incorporated into manufacturing product exporting to the EU.

If a farm is out of compliance with EU regulations at the end of the 12-month period, a renewal derogation must be submitted, and the raw milk supplier must maintain the Affidavit for Producer Corrective Action. All Affidavit for Producer Corrective Action forms should be available for review during an AMS EU-EVP Audit.

Table 3: Example – First Time SCC Notification and Derogation

Reporting Month	Reporting month is calculation data from previous 3 months results	If rolling geometric mean is >400,000/ml	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 consecutive month after submission of notification)

Table 4: Example – First Time Bacterial SPC Notification and Derogation

Reporting Month	Reporting month is calculation data from previous 2 months, 2 samples per month	If rolling geometric mean is >100,000/ml	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	**Milk NOT ok for export in April**. Milk supplier must suspend, segregate, discontinue certification or request derogation. (3rd consecutive month after submission of notification)

The milk supplier must take steps to request a derogation from AMS Dairy Program or exclude the milk from being used to manufacture EU products 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 6 months of the notification month.

Additional helpful information related to derogation requests can be found at the EU Dairy Export Certification Program website.

12. Special Considerations:

12.1 Colostrum and Colostrum-based Product Certificates:

Colostrum and colostrum-based products are exempt from the SCC and bacterial SPC requirements of Regulation 853/2004. **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 colostrum 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" or comparable state regulations. Colostrum must also be sourced from farms that have not administrated any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022, as applicable for consignments certified for entering the European Union from 3 September 2026.

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 Export 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)

12.2 EU Transit Certificates:

Shipments transiting the EU to other countries outside the EU require transit certificates containing only the animal health attestations. This means the public health attestations relating to the SCC and bacterial SPC requirements of Regulation 853/2004 are not applicable, including the antimicrobial attestations. Please note, even though the SCC and bacterial SPC requirements and antimicrobial requirements are not required 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 or comparable state regulations.

Transit certificates will still be subject to an AMS EU-EVP Audit to verify the raw milk sourced for applicable dairy ingredients was supplied by credentialed farms. Retention of records shall not be required beyond three years. These records must be available during an AMS EU-EVP Audit.

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:

- 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 an FDA Establishment Identifier (FEI) number

The identification number from the appropriate 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 control post personnel often review this information for consistency.

12.3 United Kingdom Certificates:

On January 1, 2021, the United Kingdom (GB) completed its departure from the EU. The United Kingdom of Great Britain and Northern Ireland (NI), includes the devolved nations of England, Wales, Northern Ireland, and Scotland. 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 United Kingdom, 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 United Kingdom."

AMS will issue certificates for the following United Kingdom export certificates for which dairy is the final product.

- **GBHC 412 (formerly 66X)**- Dairy products from non-EU countries Model health certificate for dairy products derived from milk of cows, ewes, goats and buffaloes for human consumption from third countries or parts thereof authorized in column B (Milk-HTB) GBHC412 v1.1 Aug-23
- **GBHC 415 (formerly 69X)**-Transit or storage of milk, colostrum, dairy products or colostrum-based Model health certificate for raw milk, colostrum, dairy products or colostrum-based products for human consumption, intended for transit or storage (M/C/DP-T/S) GBHC415 v1.1 Aug-23
- **GBHC 411 (formerly 65X)**-Dairy products derived from raw milk products from non-EU countries Model certificate for dairy products derived from raw milk for human consumption, from third countries or parts thereof authorized in column A (Milk-RMP) GBHC411 v1.1 Aug-23
- **GBHC 414 (formerly 68X)**- Colostrum and Colostrum-Based Products Model health certificate for colostrum of cows, ewes, goats and buffaloes and colostrum-based products derived from colostrum of the same species from third countries or parts thereof listed in column A for human consumption (C/CPB) GBHC414 v1.1 Aug-23
- **GBHC 440 (formerly 88X)**-Composite products intended for human consumption from non-EU countries Model health certificate for composite products intended for human consumption (COMP) GBHC440 v1.1 Aug-23
- **GBHC 441 (formerly 89X)**-Transit or storage of composite products intended for human consumption from non-EU countries Model health certificate for transit or storage of composite products intended for human consumption (COMP-T/S) GBHC441 v1.1 Aug-23

United Kingdom certificate applications should have CoCs available for each step in the supply chain confirming the SCC. Milk from non-Grade A farms must confirm SCC and bacterial SPC results. Examples of CoCs are in **Appendix B** of this document. Shipments to the United Kingdom do not need to maintain **Appendix C** of this document.

Important Note: The United Kingdom has a strict requirement that all GB export certificates be issued

prior to a shipment's departure date from the United States. Be sure to request GB certificates to allow time for processing/issuance prior to the departure date.

12.4 Turkey Certificates:

AMS will issue a Dairy Veterinary Health Certificate for exported dairy products derived from milk of cows, ewes, goats, and buffaloes, intended for human consumption from the United States to the Republic of Turkey.

Beginning January 1, 2026, all dairy products, dairy ingredients, and composite products exported to Turkey must come from approved establishments. Any facility involved in the manufacturing, processing, or packaging of dairy products or dairy ingredients, whether as a final product or as part of a composite product, must be listed in the "List of U.S. Establishments Eligible to Export Dairy Products to the European Union (EU TRACES). Exporters should ensure that all relevant facilities are included on this list prior to shipping to Turkey.

Turkey certificate applications should have CoCs available for each step in supply chain. Examples of CoCs are in **Appendix B** of this document. Monthly SCC rolling geometric mean results for Grade A milk must be maintained with the Raw Milk Supplier records. As applicable, both monthly rolling geometric mean results for SCC and bacterial SPC records must be available for milk from non-Grade A farms. Turkey certificates do not require the antimicrobial affidavit to be completed from **Appendix C**.

Important Note: Turkey has a strict requirement that all Turkey export certificates be issued prior to a shipment's departure date from the United States. Be sure to request Turkey certificates to allow time for processing/issuance prior to the departure date.

12.5 EU Composite Certificates:

For the COMP – Chapter 50 export 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 export 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 <u>not</u> 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.

Composite product previous de minimis thresholds have been replaced by complex risk-based criteria (e.g., shelf stable vs non shelf stable). The title of the Chapter 50 and 52 certificates note they are required for (a) non-shelf-stable composite products and (b) shelf-stable composite products containing any quantity of (i) meat products (except gelatine) not derived from ruminant bones (ii) collagen not derived from ruminant bones, (iii) collagen not derived from ruminant bones and highly refined products, and (ix) any quantity of colostrum-based products. Shelf-stable products not containing ingredients noted in section b of the above statement may enter the EU with the private attestation in

Annex V of Commission Implementing Regulation (EU) 2020/2235. The private attestation does not require U.S. government endorsement.

Exporters are urged to review additional guidance from multiple sources to verify the type of certificate(s) 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 can be found in the References section. Composite product manufacturers are not currently required to attest to the antimicrobial statement in the CoC and may strike it out; however, a CoC must still be maintained.

13. Imported Dairy Ingredients into the United States:

Applicants utilizing imported dairy products and dairy ingredients intended to be used to produce dairy products that will be shipped to the EU must:

- Ensure the manufacturing facility is on the EU IMSOC website-approved dairy facility list for the country of origin, and
- Upload the 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 will meet this requirement with the application. If a supplier has an imported dairy ingredient in their dairy product, the certificate issued by the competent authority of the country of origin must be provided for review during an audit.

14. AMS EU-EVP Audits:

AMS EU-EVP Audits include a sampling review of European Union, United Kingdom, and Turkey certificates. All businesses applying for export certificates, manufacturing or processing dairy products or ingredients, supplying dairy products or ingredients, or supplying raw milk for any dairy products or ingredients further exported to the EU will be subject to AMS EU EVP Audit to verify compliance with EU regulations, to confirm compliance with the attestations listed on the export certificate, to verify the information provided on the request, to ensure CoCs are valid, and SCC and/or bacterial SPC requirements. By submitting the request, you are certifying you have documentation to verify the product meets the EU requirements and all information on the EU Export Certificate. Applicants will be billed for the AMS EU-EVP Audit and subsequent follow up audit(s), as applicable.

During an AMS EU-EVP Audit, it is the customer's responsibility to maintain traceable documentation both forward to the final exporting destination and back one step in the supply chain towards the raw milk source. The documentation must be available to auditors for review.

Auditors will also confirm the certificates of conformance are being accurately utilized and maintained during the dairy product trace.

Auditors will verify that 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 or comparable state regulations. Entities throughout the supply chain are expected to maintain records to demonstrate milk used for export to the EU was sourced from farms regulated under one of these programs.

Records containing adequate information to trace back at least one step toward the raw milk source for product(s) covered by the EU Export 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:

A. 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, and to
B. Milk processor implementation protocols ensuring the raw milk is sourced from farms that have not administrated any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022, as applicable for consignments certified for entering the European Union from 3 September 2026.

15. References:

- Affidavit for Producer Corrective Action
- Annual Turkey FAIRS Country Report June 20, 2025
- ATLAS Platform
- Commission Delegated Regulation 2020/692
- Commission Delegated Regulation 2023/905
- Commission Delegated Regulation 2023/905
- Commission Implementing Regulation 2019/627
- Commission Implementing Regulation 2020/2235
- Commission Implementing Regulation 2022/1255
- Commission Implementing Regulation 2024/2598
- Commission Implementing Regulation 2024/2598
- Commission Implementing Regulation 2024/399
- Commission Implementing Regulation 2025/636
- EU Dairy Export Certification Website
- EU entry conditions for composite products
- EU Regulation 2016/429
- EU Regulation 2017/625
- EU Regulation 852/2004
- EU Regulation 853/2004
- European Union IMSOC/TRACES List
- FDA Export Listing Module
- Federal Register Rate Charges for AMS Services
- Grade 'A' Pasteurized Milk Ordinance (PMO)
- Import of composite products into the EU Questions & Answers Version 18 December 2024
- List of establishments eligible to export animal products to the UK
- List of U.S. Establishments Eligible to Export Dairy Products to the EU (IMSOC/TRACES)
- Raw milk, dairy products, colostrum and colostrum-based products
- Training on the new Agriculture Trade Licensing & Attestation Solution System | Agricultural Marketing Service (usda.gov)
- USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements

16. Appendix A. SCC and SPC Calculation:

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 Program's certification will recognize rolling geometric means of results from individual farm's raw milk samples 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.

Monthly SCC Count	**Geometric Mean**
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.

Bacterial SPC Average Values	**Geometric Mean**
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

17. Appendix B. Certificates of Conformance:

Exhibit 1.1

Certificate of Conformance for Applicants

The Certificate of Conformance shall be provided on company letterhead that includes company name, physical manufacturing facility 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.
***If requesting a EU Transit certificate, Turkey, or United Kingdom export certificate, the antimicrobial statement in paragraph two does not apply**.

Certificate of Conformance

Applicant for European Union Export 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), the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements, or comparable state regulations.

I hereby certify that as applicable for consignments certified for entering the European Union from 3 September 2026, the source animals from which raw milk was obtained to produce the dairy products and/or dairy ingredients in this consignment have not been administered any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022.

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 Certificates 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:

Manufacturing plant name and full address	Plant ID number on EU List	Product Name	Lot numbers	Manufacturing Dates

Exhibit 1.2

Certificate of Conformance for Dairy Processor or Manufacturer

The Certificate of Conformance shall be provided on company letterhead that includes company name, physical manufacturing facility 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.
***If requesting a EU Transit certificate, Turkey, or United Kingdom export certificate, the antimicrobial statement in paragraph two does not apply**.

Certificate of Conformance

Processors of 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), the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements, or comparable state regulations.

I hereby certify that as applicable for consignments certified for entering the European Union from 3 September 2026, the source animals from which raw milk was obtained to produce the dairy products and/or dairy ingredients in this consignment have not been administered any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022.

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:

Manufacturing plant name and full address	Plant ID number on EU List	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, representing facility 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.
***If requesting a EU Transit certificate, Turkey, or United Kingdom export certificate, the antimicrobial statement in paragraph two does not apply**.

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

Furthermore, I hereby certify that as applicable for consignments certified for entering the European Union from 3 September 2026, the source animals from which raw milk was obtained to supply your facility have not been administered any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022.

Signature	**Date**
Printed Name	**Title**
Email Address	

Period [1]covered by Certificate of Conformance, not to exceed one month:

Beginning Date	End Date

[1] Raw Milk suppliers are required to maintain monthly Standard Plate Count or Somatic Cell Count rolling geometric means in addition to being on an Approved Exporting List.

Exhibit 1.4

Certificate of Conformance Composite Products

The Certificate of Conformance shall be provided on company letterhead that includes company name, physical manufacturing facility 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), the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements, or comparable state regulations.

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:

Manufacturing plant name and full address	Plant ID number on EU List	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 manufacturing facility 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 Export 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), the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements, or comparable state regulations.

I hereby certify that as applicable for consignments certified for entering the European Union from 3 September 2026, the source animals from which colostrum was obtained to produce the dairy products and/or dairy ingredients in this consignment have not been administered any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022.

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:

Manufacturing plant name and full address	Plant ID number on EU List	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 manufacturing facility 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), the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements, comparable state regulations.

I hereby certify that as applicable for consignments certified for entering the European Union from 3 September 2026, the source animals from which colostrum was obtained to produce the dairy products and/or dairy ingredients in this consignment have not been administered any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022.

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:

Manufacturing plant name and full address	Plant ID number on EU List	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 manufacturing facility 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.

[2]This Certificate of Conformance is valid for a period of one year from the signature date.

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), the USDA AMS Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements or comparable state regulations. Furthermore, I hereby certify that as applicable for consignments certified for entering the European Union from 3 September 2026, the source animals from which raw milk was obtained to supply your facility have not been administered any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022.

Signature	**Date**
Printed Name	**Title**
Email Address	

[2] Colostrum suppliers are not required to maintain Standard Plate Count or Somatic Cell Count rolling geometric means. Colostrum suppliers must on an Approved Exporting List.

18. Appendix C: Antimicrobial Resistance Affidavit

Antimicrobial Resistance Affidavit for Raw Milk Suppliers:

This Antimicrobial Resistance Affidavit shall be provided on company letterhead that includes company name, representing facility address, email address, contact name, and phone number. This Antimicrobial Resistance Affidavit must be shared with dairy producers every 12-months for any shipments of milk used in product manufactured for shipment to the EU. The organization will describe how the dairy producers were informed. The example below lists raw milk. For colostrum affidavits, replace the word "milk" with "colostrum."

This Affidavit is valid for a period of one year from the signature date.

Antimicrobial Resistance Affidavit

I, _____(COMPANY REPRESENTATIVE), as the person responsible for [preferred description of activity e.g. procurement, quality, quality assurance, etc.] _____ of raw milk supplied by_____ (ORGANIZATION NAME), hereby certify that, as applicable, for consignments certified for entering the European Union from 3 September 2026, the source animals from which raw milk was obtained have not been administered any of the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022. _____ (ORGANIZATION NAME) has informed all raw milk producers that the antimicrobials listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 are prohibited via _____ (In this section, the ORGANIZATION would specify how the dairy producer was informed; For example, by letter, by including text in the farmer's contract, etc.).

Signature	**Date**
Printed Name	**Title**
Email Address	

19. Appendix D: EU Antimicrobial List:

The Annex to Commission Implementing Regulation (EU) 2022/1255 of July 19, 2022, prohibits the use of the following antimicrobials in veterinary medicinal products or medicated feed. Enforcement in third countries begins with shipments certified for entering the EU starting 3 September 2026. Dairy products with export certificates signed on or after 3 September 2026 must have documentation confirming that the source animals have not been treated with the antimicrobials listed below.

- Carboxypenicillins
- Ureidopenicillins
- Ceftobiprole
- Ceftaroline
- Combinations of cephalosporins with beta-lactamase inhibitors
- Siderophore cephalosporins
- Carbapenems
- Penems
- Monobactams
- Phosphonic acid derivates
- Glycopeptides
- Lipopeptides
- Oxazolidinones
- Fidaxomicin
- Plazomicin
- Glycylcyclines
- Eravacycline
- Omadacycline
- Amantadine
- Baloxavir marboxil
- Celgosivir
- Favipiravir
- Galidesivir
- Lactimidomycin
- Laninamivir
- Methisazone/metisazone
- Molnupiravir
- Nitazoxanide
- Oseltamivir
- Peramivir
- Ribavirin
- Rimantadine
- Tizoxanide
- Triazavirin
- Umifenovir
- Zanamivir
- Nitazoxanide