

European Health Certification Program

These instructions establish the responsibilities and procedures 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 which outlines the requirements for the export of dairy products from the United States to the EU. The major difference between the United States and EU milk requirements is the maximum limit on somatic cell and bacterial standard plate counts for the raw milk.

At the time of this issuance, the following 28 countries are members of the European Union:

| | | | |
|-----------|----------------|----------|-----------------|
| Austria | Belgium | Bulgaria | Croatia |
| Cyprus | Czech Republic | Denmark | Estonia |
| Finland | France | Germany | Greece |
| Hungary | Ireland | Italy | Latvia |
| Lithuania | Luxembourg | Malta | The Netherlands |
| Poland | Portugal | Romania | Slovakia |
| Slovenia | Spain | Sweden | United Kingdom |

In addition, the following EU aligned countries accept EU certificates:

| | | | |
|---------|---------------|--------|-------------|
| Iceland | Liechtenstein | Norway | Switzerland |
|---------|---------------|--------|-------------|

I. 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 that are readily recognized as a dairy product, or require in their standard of identity that they originate from milk, will require an EU health certificate. In addition, composite milk products that either utilize a dairy product as a characterizing effect, or contain dairy ingredients as an essential part of the product, generally will require certification if exported to the EU. Decision 2007/275/EC states that foodstuffs containing more than 50% milk products should be accompanied by EU health certificates. Where uncertainty exists as to which composite milk products require certification for export to the EU, the applicant should contact the appropriate regulatory authority in the receiving country or their importer to determine if a certificate is needed. Examples of dairy products and composite products that require certification are:

| | | | |
|----------------------------|------------|--------------------------|-----------|
| Milk | Cream | Butter | Cheese |
| Yogurt | Buttermilk | Kefir | Caseins |
| Butter Oil | Lactoserum | Dairy Fat Material | Ice Cream |
| Partially Dehydrated Milks | | Totally Dehydrated Milks | |

Examples of composite products identified as containing only a minimum part of milk or milk product and that generally do not require certification under Regulation (EC) No 853/2004 are:

| | | | |
|----------------|-----------------|---------------------|----------|
| Milk Chocolate | Butter Crackers | Salad Dressing | Cupcakes |
| Whiskey Cream | Breton Crepes | Creamed Tomato Soup | |

II. Dairy Plant Reference List

All domestic plants producing dairy or related products, that manufactured the product in the final package, for export to the European Union must be identified on the “*Dairy Plant Reference List*” established by the FDA and accepted by the EU. This list is maintained by the FDA and updated periodically. The current Dairy Plant Reference list can be found at: https://webgate.ec.europa.eu/sanco/traces/output/US/MMP_US_en.pdf

Dairy plants that supply dairy product(s) or dairy ingredient(s) to an applicant but do not ship dairy product directly to the EU are not required to be on the “*Dairy Plant Reference List*” but will be subject to AMS Dairy Programs reviews of records to verify compliance with EU somatic cell and bacterial standard plate count requirements

Plants wishing to request inclusion on this list can do so by contacting:

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Safety
Division of Plant and Dairy Food Safety
Dairy and Egg Branch
Phone: 240.402.1485
Fax: 301.436.2632
5100 Paint Branch Pkwy
College Park, MD 20740

III. Commission Regulations (EC) No 852/2004, 853/2004 and 854/2004

The requirements for dairy products imported into the EU are detailed in Council Regulations (EC) No [852/2004](#), [853/2004](#) and [854/2004](#). These comprehensive regulations address many issues relative to milk production and processing. Countries outside of the EU that wish to import dairy products to that market are required to provide certificates that indicate compliance with these regulations.

Milk produced and dairy products manufactured under the United States system provide safeguards at least equivalent to the requirements of Regulations (EC) No 852/2004, 853/2004 and 854/2004. There are two quality-related differences in the two systems: 1) the EU somatic cell count and bacterial standard plate count requirements that apply at the farm level and 2) the method for calculating somatic cell count and bacterial standard plate count averages (rolling geometric mean). To certify dairy product shipments to the EU, AMS Dairy Programs requires dairy product manufacturers to certify compliance with the somatic cell count and bacterial standard plate count 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 somatic cells per 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 bacteria per ml.

Grade A cow's milk and Grade B cow's milk in the U.S. are regulated at maximum somatic cell counts of 750,000 per ml. Grade A milk in the U.S. is regulated at a bacterial standard plate count of 100,000 or less. The recommended regulatory bacterial standard plate count for 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 grades of milk for somatic cell count and Grade B milk for bacterial standard plate counts). Plants with a Grade A milk supply that supply ingredients or raw milk are generally exempt from requirements to keep additional records on bacterial standard plate counts to confirm compliance with Regulation (EC) No 853/2004.

IV. Applicant's Responsibility

The applicant shall apply for and obtain an EU Health Certificate for products containing milk and/or milk products destined to the EU. The applicant shall ensure that the manufacturing plant that puts the product in the final package for export is included on the "*Dairy Plant Reference*" list (See [Section B.2.b "*Dairy Plant Reference List*"](#)).

The applicant shall maintain records that demonstrate compliance with EU raw milk requirements to trace back at least one step in the supply chain (toward the raw milk producer) for all dairy products and all applicable dairy ingredients intended for export to the EU. The applicant is responsible for the records to trace the final product back to the raw milk. The applicant will be subject to AMS Dairy Programs reviews of records to verify compliance with EU somatic cell and bacterial standard plate count requirements**.

If AMS is not able to trace records back to the raw milk that demonstrate compliance with EU regulation 853/2004 the applicant shall be restricted from receiving future EU certificates.

Dairy plants that supply dairy product(s) or dairy ingredient(s) to an applicant but do not ship dairy product directly to the EU are not required to be on the "*Dairy Plant Reference List*" but will be subject to AMS Dairy Programs reviews of records to verify compliance with EU somatic cell and bacterial standard plate count requirements**.

** AMS Dairy Programs will charge for the AMS Dairy Programs review of records. The applicant for the EU health certificate is responsible for the charges. However if a supplier provides product to multiple applicants, AMS may charge the supplier for the service. The charges will be for the total number of hours, plus travel time and expenses, at the current *Federal Register* published rate for Dairy Program services.

Applicants that utilize imported dairy products and dairy ingredients intended to be used for the production of products that will be shipped to the EU must present an EU Milk HTB certificate issued by the competent authority of the country of origin certifying that these imported dairy products and ingredients meet all the requirements of Regulation (EC) No 853/2004 including somatic cell and bacterial standard plate counts for raw milk. This requirement for an EU Milk HTB certificate includes dairy products/dairy ingredients imported from the EU member states and countries maintaining equivalency agreements with the EU.

The applicant shall submit the following information to AMS Dairy Programs for issuance of an EU Health Certificate:

- Certificate of Conformance on company letterhead signed by a responsible official for the applicant (See [Exhibit 1.B](#)) or the electronic equivalent.
- All product information requested on the “Instructions for Completion of Health Certificate Worksheet for Export Certificates to the European Union.” (See [Exhibit 1](#))
- Each request for an EU Health Certificate shall include enough information to trace back at least one step toward the raw milk production for products covered by the EU Health Certificate. This can include production lot identification codes, production dates, bills of lading or any other documentation that provides this information. This information is necessary to certify compliance with (EC) No 853/2004 during AMS Dairy Programs review of records.

The EU Health Certificate can be requested over the internet at the AMS Dairy Programs website at: <http://www.ams.usda.gov/services/imports-exports/eu-dairy-exports>. If the applicant request the certificate online the requirement for a COC is fulfilled by the check boxes on the bottom of the request.

If the information necessary to facilitate at least one step trace back toward the raw milk production certified is not included, the issuance of an EU Health Certificate will be denied until the information is provided.

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

An applicant who fails to maintain adequate records and COCs that substantiate each request for an EU Health Certificate, as determined during an AMS Dairy Programs review of records, will immediately be ineligible to receive EU Health Certificates. To reestablish eligibility, an AMS Dairy Programs review of records will be conducted to determine if adequate records and COCs are maintained to tie the product in the final package for export to raw milk that is in compliance with 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 and establishment numbers on product containers and shipping container seal numbers documented on the EU Health Certificate are required by some importing countries or port authorities. 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 processors and the milk suppliers involved in the production of the product that was certified for shipment to the EU; must maintain records documenting compliance with EU somatic cell count and bacterial standard plate count 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.

Minor Ingredients

According to decision 2007/275/EC foodstuffs containing more than 50% of dairy products should be accompanied by sanitary certificates for milk and milk products. Minor dairy ingredients making up a composite food may not require an EU Health Certificate. The requirement for certification is under the control of the importing country.

V. Responsibility of Processors of Dairy Ingredients and/or Products

The requirements for a processor where the dairy ingredient or composite food requires an EU Health Certificate are:

- A. The processor has on file and available for AMS Dairy Programs review of records COCs from their dairy ingredient supplier(s) demonstrating the dairy product(s)/dairy ingredient(s) meet Regulation (EC) No 853/2004 for somatic cell and bacterial standard plate count requirements. The processor's COCs(see [Exhibit 1.B.2](#)) 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 the somatic cell and bacterial standard plate count requirements of Regulation (EC) No 853/2004 (See Exhibit 1.B),
 - The dates the dairy product(s)/dairy ingredient(s) (for which the COC is issued) 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 COC was signed.
- B. 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 EU Health Certificate issued by the sovereign government of the exporting country providing the same assurance as the certificate issued by AMS Dairy Programs (see [Exhibit 2](#), "EU Health Certificate"). This includes dairy product(s)/dairy ingredient(s) imported from the EU or countries maintaining equivalency agreements with the EU.
- C. Records shall be retained that provide (i) a COC that includes enough 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** (ii) any other documentation which can demonstrate the conformance of the somatic cell and bacterial standard plate counts to the EU requirements.

Retention of Records

The applicant for the EU health certificate, the processors and the milk suppliers involved in the production of the product that was certified for shipment to the EU; must maintain records documenting compliance with EU somatic cell count and bacterial standard plate count 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 Programs review of records.

Minor Ingredients

According to decision 2007/275/EC foodstuffs containing more than 50% of dairy products should be accompanied by sanitary certificates for milk and milk products. Minor dairy ingredients making up a composite food may not require an EU Health Certificate. The requirement for certification is under the control of the importing country.

VI. Milk Supplier's Responsibility

AMS Dairy Programs will review the system used by the milk supplier (for example: cooperative, direct shipper, milk shipper (the entity with farm records), proprietary processor, dairy milk marketer, etc.) that supplied milk for processing to verify compliance with somatic cell and bacterial standard plate count requirements of Regulation (EC) No 853/2004 and 854/2004. The milk supplier shall have records of individual farms available to confirm that raw milk meeting the somatic cell and bacterial standard plate count requirements of the EU is received at the facilities manufacturing dairy products for shipment to the EU. While a number of different compliance systems devised by the milk supplier may result in compliance with the requirements of Regulation (EC) No 853/2004 and 854/2004, AMS Dairy Programs considers the following minimum requirements:

- A. The milk supplier shall test all farms whose milk or milk products could be incorporated into product in the 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 standard plate count and one sample per month for somatic cell count. Calculation of bacterial standard plate count means (arithmetic or geometric; hereafter referred to as "mean") will be based on a rolling two-month time period. Calculation of somatic cell count mean will be based on a rolling three-month time period.

(Note: At the implementation of these instructions for the European Health Certification Program all farms will be given three months to establish initial means for somatic cell counts and two months to establish initial means for bacterial standard plant counts. Startup farms and farms that transfer between milk suppliers will be given three months to establish a somatic cell count mean and two months to establish a bacterial standard plate count. The old instructions will continue to be used until an initial mean is established for each farm.)

1. If a farm's rolling mean for either the somatic cell count or the bacterial standard plate count exceeds the maximum EU requirements, the milk supplier must notify AMS Dairy Programs 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 Programs, as demonstrated in the chart below:

| 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. (1 st month) |
| March | Dec, Jan, Feb | > 400,000 | Milk ok for export in Mar. (2 nd month) |
| April | Jan, Feb, Mar | > 400,000 | <u>Milk NOT ok for export in April.</u> Milk supplier must suspend, segregate, discontinue certification or request derogation. (3 rd month) |

(AMS would expect the Milk Supplier to take steps to request derogation or exclude the milk from EU certification when they receive the April numbers (That is in early May). AMS will accept derogations as applying retroactively if the milk supplier makes the request in a reasonable time frame.)

The milk supplier must

- (1) suspend pick up of milk from the farm; **or**
 - (2) segregate the products made from that milk from the products that comply with EU requirements; **or**
 - (3) discontinue certifying that products made with this milk meet the requirements of Regulation (EC) No 853/2004; **or**
 - (4) at the request of the farm, contact AMS Dairy Programs and ask for a derogation (deviation under special circumstances) to allow this milk to be accepted into the EU export program at <https://www.etde.usda.gov/etde/>. A derogation will be granted provided that during processing the milk or milk products are (i) pasteurized **or** (ii) made into raw milk cheese that will be aged at least 60 days before being placed on the market. Corrective actions and out-of-compliance monitoring activities are expected to continue during the derogation period, which is valid for one year. In the event of a farm's continued non-compliance, the derogation must be reapplied for one year following the issuance of the derogation.
3. A milk supplier, at the request of the farm, may request from AMS Dairy Programs a “seasonal derogation”*. A seasonal derogation will be granted to a farm that can demonstrate for a majority (at least 9 months) of the year they are in compliance with the EU requirements for somatic cell count; only due to seasonal variations is the farm’s somatic cell count escalated for a period of time during the year. The farm must be able to demonstrate through records that this variation is truly seasonal and not the result of poor hygiene or sanitary procedures. All seasonal derogations will be reviewed during the AMS Dairy Programs review of records to verify compliance with EU regulations. Seasonal derogations must be renewed every three years.

- B. The milk supplier shall provide (i) a Certificate of Conformance (COC)(see [Exhibit 1.B.3](#)) that can be used to link products exported to the EU with raw milk somatic cell counts and bacterial standard plate counts of the milk used to produce those products to provide verification of compliance to Regulation (EC) No 853/2004, **or** (ii) any other documentation which can demonstrate the conformance of the somatic cell and bacterial standard plate counts to the EU requirements. At a minimum, this would indicate the timeframe for which the COC covers. As an example, a COC covering raw milk delivered in March would be based on February’s compliant three-month rolling mean.
- C. To verify compliance with EU requirements (EC) 853/2004 and 854/2004, AMS Dairy Programs will conduct a review of records. This review will verify COCs provided by the milk supplier demonstrate compliance with EU requirements. During the review, at least 10% 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 (i.e., per point D.1.b.2, farms voluntarily segregated as being non-compliant with EU regulations will not be included in the review).

Through any of the above procedures, the milk supplier will be able to confirm that the somatic cell and bacterial standard plate count means for milk used to make the product in the final package for export to the EU meets the requirements of the EU.

VII. Renewing Derogations

The following procedures will be followed for renewing (non-seasonal) derogations. Seasonal derogations cover a period of three years.

A. Determining if an Immediate Renewal of Derogation is Required

Derogations are valid for a period of one year, and must be renewed if milk quality continues to fall outside of the European Union Requirements. Derogations are applied retroactively if the milk supplier makes the request in a reasonable time frame (see Program Instructions, “VI. Milk Supplier’s Responsibility” part A.2.).

When the derogation expires, if the farm’s rolling mean is in compliance with EU requirements for Somatic Cell Count (SCC) which is 400,000 cells/ml or less and Standard Plate Count (SPC) is 100,000 cells/ml or less, then no notification or request for derogation to AMS is required. Monitoring activities and calculation of rolling means will continue as described in Program Instructions “VI. Milk Supplier’s Responsibility”.

1. Requirements for Derogation Renewal.

- a) For a farm to be eligible for renewal of a derogation, one of the following must occur:
- (1) Acknowledgement of at least two corrective actions shall be documented for the second derogation (i.e., for the first renewal after the initial derogation).

- (2) The farm was in full compliance for at least one month since its last derogation. (The rolling mean decreased below 400,000 cells/ml for those farms with a SCC derogation or below 100,000 cells/ml for those farms on SPC derogation.)
- (3) The current rolling Geometric Mean (GM) is less than the GM for the same months a year earlier, i.e., May, June, and July of 2012 compared with May, June, and July of 2013, where the GM for 2013 is less.

b) Additionally, the farm must hold an active permit for producing milk issued by the State.

2. Corrective Actions

When a farm is out of compliance and operating under a derogation, out of compliance monitoring and progress on the corrective action plan is expected to continue during the derogation period.

The following are examples of appropriate corrective actions a farm may conduct to bring their counts into compliance. (List is not comprehensive):

- Develop an action plan to reduce SCC /SPC.
- Review milking equipment condition and sanitation protocols
- Consult with a local veterinarian or extension agent
- Consult with the milk supplier representative or field staff
- Review and update milking routine protocols, as necessary
- For SCC
 - o Review or update a mastitis control program
 - o Routinely sample individual cow milk for SCC
 - o Review or update culling program, emphasizing cows with a high SCC or mastitis

To be eligible for subsequent renewals the farm must be able to demonstrate that the corrective actions are improving the milk quality (as defined in Section VII.A subpart 1.a)(2) or (3)) or show that new or additional corrective actions are being implemented. All corrective actions must be disclosed on the "Affidavit for Producer Corrective Action" or a similar form. This documentation will be reviewed during the AMS Dairy Programs review of records to verify compliance with EU regulations.

***AMS will charge the milk supplier an administrative fee of 2 hours at the current *Federal Register* published rate for Dairy Program services for each derogation (seasonal or otherwise) and derogation renewal application.**

Example: Determining When Renewal of a Derogation is Required

A milk supplier was granted SCC derogations for Farms “A”, “B”, “C”, “D” and “E” in May 2012. These derogations will expire on April 30, 2013. When the April 2013 numbers are received (in early May), the rolling 3-month means for SCC are greater than 400,000. The milk supplier reviews the following data for each farm:

| Farm A | | | |
|------------|---|---|--|
| Month | Monthly data for rolling three-month mean for SCC | If result of rolling three-month mean for SCC | Actions |
| May 2013 | Feb, Mar, Apr 2013 | > 400,000 | No immediate renewal of derogation needed. Notify AMS that SCC mean was out of compliance in May. |
| April 2013 | Jan, Feb, Mar 2013 | < 400,000 | |
| Mar 2013 | Dec 2012, Jan 2013, Feb 2013 | < 400,000 | |
| Feb 2013 | Nov 2012, Dec 2012, Jan 2013 | < 400,000 | |
| Farm B | | | |
| May 2013 | Feb, Mar, Apr 2013 | > 400,000 | No immediate renewal of derogation needed. Notify AMS that SCC mean was out of compliance in May. |
| April 2013 | Jan, Feb, Mar 2013 | < 400,000 | |
| Mar 2013 | Dec 2012, Jan 2013, Feb 2013 | > 400,000 | |
| Feb 2013 | Nov 2012, Dec 2012, Jan 2013 | < 400,000 | |
| Farm C | | | |
| May 2013 | Feb, Mar, Apr 2013 | > 400,000 | No immediate renewal of derogation needed. Notify AMS that SCC mean was out of compliance in April. <i>(Note: Going forward, if also high in June and July, a derogation will need to be requested.)</i> |
| April 2013 | Jan, Feb, Mar 2013 | > 400,000 | |
| Mar 2013 | Dec 2012, Jan 2013, Feb 2013 | < 400,000 | |
| Feb 2013 | Nov 2012, Dec 2012, Jan 2013 | < 400,000 | |
| Farm D | | | |
| May 2013 | Feb, Mar, Apr 2013 | > 400,000 | No immediate renewal of derogation needed. Notify AMS that SCC mean was out of compliance in March. <i>(Note: Going forward, if also high in June, a derogation will need to be requested.)</i> |
| April 2013 | Jan, Feb, Mar 2013 | > 400,000 | |
| Mar 2013 | Dec 2012, Jan 2013, Feb 2013 | > 400,000 | |
| Feb 2013 | Nov 2012, Dec 2012, Jan 2013 | < 400,000 | |
| Farm E | | | |
| May 2013 | Feb, Mar, Apr 2013 | > 400,000 | Immediate renewal of derogation needed. Request renewal from AMS. |
| April 2013 | Jan, Feb, Mar 2013 | > 400,000 | |
| Mar 2013 | Dec 2012, Jan 2013, Feb 2013 | > 400,000 | |
| Feb 2013 | Nov 2012, Dec 2012, Jan 2013 | > 400,000 | |

**Affidavit for Producer Corrective Action
for Somatic Cell Count Derogation Renewal**

I, _____, hereby state and affirm that I am a bona fide milk producer and a member of (*milk supplier*), Member # _____. I am responsible for the milk production marketed under this (*milk supplier*) membership.

I make this statement of my own free will, absent of any threat, promise or inducement, whether real or implied:

1. During the past twelve months, I have made a good faith attempt to reduce my somatic cell count by performing the action(s) indicated:

Action plan developed in consultation with _____, (*milk supplier*) field staff and/or other qualified individual(s)

Initial

Reviewed/updated mastitis control program with _____, veterinarian and/or other qualified individual(s)

Initial

Reviewed milking equipment condition/sanitation protocols with _____, equipment manufacturers and/or other qualified individual(s)

Initial

Reviewed/updated milking routine protocols with _____, veterinarian and/or other qualified individual(s)

Initial

Routinely sampled individual cow milk for somatic cell count

Initial

Initial

Reviewed/updated culling program with emphasis on cows with history of high somatic cell count or mastitis

Initial

Other reasonable effort(s) to reduce somatic cell count (insert description): _____

2. I understand that one or more parties may rely upon the representations that I am making in this Affidavit. I hereby authorize (*milk supplier*) to disclose the fact that I have executed this Affidavit to customers to whom my milk is marketed.
3. I hereby acknowledge that from time to time (*milk supplier*) may be required to disclose the fact that I have executed this Affidavit to government or regulatory entities as required by law.
4. I understand that my eligibility for derogation under the USDA-AMS EU Health Certification Program is contingent upon the truthfulness of my responses herein and the completion of the actions to which I have attested.

I hereby swear and attest that the above is my true and valid statement.

Dated this _____ day of _____, _____.

Signature

Printed name

Retention of Records

The applicant for the EU health certificate, the processors and the milk suppliers involved in the production of the product that was certified for shipment to the EU; must maintain records documenting compliance with EU somatic cell count and bacterial standard plate count 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 Programs review of records.

VIII. Special Considerations for Sanitary Certification to U.S. Military Installations in the European Union

Shipments to US military installations in the EU only require the animal health attestations. This requirement can be met by the EU Animal Health Transit Certificate. The public health requirements are satisfied the same as if the military installation were in the United States. The products certified will not be sold to the general public in Europe. See [Exhibit 3](#). Transit certificate for Belgium and Ireland are issued by Animal and Plant Health Inspection Service (APHIS).

Appendix A. Calculation of Rolling Geometric Mean (G.M.)

The EU uses a rolling geometric mean to determine compliance with the somatic cell and bacterial standard plate count 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 somatic cell count and twice per month over a two-month period for bacterial standard plate counts.

(Note many calculators have a key labeled “X^{1/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.)

Somatic Cell Count Example Calculations:

- A. Determine the farm’s somatic cell count 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 Somatic Cell 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 |

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

G.M. = 348,000 for Month#3

Bacterial Standard Plate Count 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 standard plate count 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 Standard Plate Count 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 |

$$G.M. (Bact.) = \sqrt[4]{Month1_1 \times Month1_2 \times Month2_1 \times Month2_2}$$

G.M. = 24,100 for Month #2

Instructions for Completion of Health Certificate Worksheet for Export Certificate to the European Union

General Information

Applicants requesting EU Health Certificates must complete a worksheet and a Certificate of Conformance (copies of blank documents are included below). Applicants are subject to annual Documentation Reviews by the Dairy Grading Branch to verify that information provided on these worksheets and Certificates of Conformance are valid. By submitting your request you are certifying that you have documentation to verify the product meets the European Union requirements and all information on the EU Health Certificate. Applicants will be billed for time and travel expenses for the Documentation Reviews and subsequent follow up Reviews.

Certificates are issued in English for countries where English is the official language. For all other EU countries the certificates are issued in dual language, English and the official language of the destination country. If an applicant wishes for the information they provide on the worksheet to be in the official language of the country of destination the applicant shall provide the information in the appropriate language and English.

Certificates are processed in the order they are received. Electronic requests are processed before faxed or mailed in requests. EU certificates can be requested electronically over the web at:

<http://www.ams.usda.gov/services/imports-exports/eu-dairy-exports>

The applicant shall provide a copy of the appropriate Certificate of Conformance with each faxed or mail 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.

All completed documents are returned to the applicants by U.S. Mail unless an express mail air bill is provided by the applicant.

The exporter cannot make changes to the certificate. Nor can alterations may be made to the certificate after the endorsement by AMS

Please fax in only the worksheet and the Certificate of Conformance. No coversheet or additional pages are needed. Mail or fax the completed worksheet and certificate of conformance to:

Export processing
USDA, Agricultural Marketing Service
Dairy, Dairy Grading Branch
Room 2746-S
1400 Independence Avenue, SW
Washington, D.C. 20250-0230

Fax Number: 202-720-2643
Phone Number: 202-720-7473

EU Health Certificates are billed at the rate of one hour at the currently published hourly rate. Certified copies will be billed at the rate of ½ hour of the currently published hourly rate. Additional services, such as faxes or special handling will result in additional charges. Current hourly rates are published in the [Federal Register](#).

Allow 5 business days for processing.

Instructions and explanations for filling out worksheet

All Worksheets with incomplete, inaccurate, or illegible information will not be processed.

Applicant

This should be the entity requesting the export certificate. The applicant must be in the Dairy Grading Branch billing system. If you are not a current applicant in the Dairy Grading Branch billing system please contact Bari Kinne at 630-437-5073 or: Bari.Kinne@ams.usda.Gov. Please put the applicant name as it is in the Dairy Grading Branch billing system.

Applicant Number

This is the applicant account number from the Dairy Grading Branch billing system. Applicant numbers can be obtained or verified from Bari Kinne at: 630-437-5073 or Bari.Kinne@ams.usda.gov.

Customer Ref

This is an optional field for the applicant's internal reference numbers. This information will appear on the monthly statement next to the charges for the export certificate. Provide information that will help identify this particular request.

Contact

Provide the name of the contact for questions regarding this certificate request.

E-Mail Address

Provide an e-mail address for the contact that correspondence regarding the certificate request can be sent.

Telephone

Provide a telephone number for the contact person including area code and country code if applicable.

Fax

Provide a fax number where information regarding the certificate request can be directed.

Contact

Provide the name of the person to whom the certificate should be addressed.

Company

Provide the name of company to which the certificate should be mailed. If the request for the certificate is by a private individual, put N/A (for not applicable) in this box.

Street

Provide the street address for the mailing address.

City

Provide the city for the mailing address.

State

Provide the state for the mailing address.

ZIP

Provide the zip code for the mailing address.

The information requested below will appear on the export certificate. The number in parenthesis corresponds to the number of the box on the actual certificate where the information will be entered.

(I.1) Consignor

Enter the full name, address and telephone number of the consignor (entity in the U.S. exporting the product).

(I.5) Consignee

Enter the full name, address, and telephone number of the consignee (entity receiving the product in the EU). The postal code is only required if it is part of the address of the consignee (some EU member states do not yet have postal codes as part of addresses). Include country codes with the phone number.

(I.7) Country of origin/ ISO code

Enter US for the country of origin and US-O for the ISO code.

(I.9) Country of destination/ISO code

Enter the EU country of destination and the appropriate ISO Code for that country.(Austria AT; Belgium BE; Bulgaria BG; Cyprus CY; Czech Republic CZ; Denmark DK; Estonia EE; Finland FI; France FR; Germany DE; Greece GR; Hungary HU; Ireland IE; Italy IT; Latvia LV; Lithuania LT; Luxembourg LU; Malta MT; Netherlands NL; Poland PL; Portugal PT; Romania RO; Slovakia SK, Slovenia SL, Spain ES; Sweden SE; and the United Kingdom/Northern Ireland GB).

(I.11) Place of origin

Enter the following information for the approved facility producing or packaging the finished product being exported (must be the same as the approved facility listed in I.28): Establishment name, complete address including city and state, and EU Approval Number. If more than one facility will be listed in I.28 put the first establishment on the list in this field.

(I.13) Place of loading

Enter the port (city and state) of exit from the U.S. (place of loading on to the ship or plane). In cases where the port of exit is not known, the location (city and state) of the warehouse from which the consignment is shipped to the port of exit may be used.

(I.14) Date of departure

Enter the date of expected consignment departure from the U.S. This should be the date the consignment will depart from the port of exit. **This date must be after the date the certificate was endorsed by USDA.**

(I.15) Means of Transport

Select the method used to transport the consignment from the U.S. to the EU. Only one method may be selected.

Identification

List the name of the shipping line or airline that is expected to be used to transport the consignment from the port of exit to the EU. The EU is believed to require the identification of a specific ship or Flight number in this box. AMS will indorse the certificate if this is left blank. However, the risk of refusal at port of the certificate due to this missing information is the shipper's.

Documentation reference

This may be left blank if the consignee is located in the EU. For transit certificates, the exporter should include the bill of lading or airway bill number.

Note: If the "Identification" or "Documentary reference" information changes after the certificate is endorsed, the exporter must notify EU officials at the border inspection Point (BIP) of the change prior to arrival of the consignment. However, the certificate does not need to be amended and AMS does not have to document the change. The exporter cannot make changes to the certificate. No alterations may be made to the certificate after the endorsement by AMS.

(I.16) Entry BIP in EU

Enter the EU Border Inspection Post (BIP). This is the port of first arrival into the EU. The official BIP code should be provided. The exporter should work with the importer to confirm that the official BIP code is used. For example, For Dublin Airport, enter "IE 02999". A list of official EU BIP code can be found in [Exhibit1.C](#) at the end of this document.

(I.18) Description of commodity

Include a general description of the exported products, e.g. milk products. This information should correspond to the HS that will be entered in block I.19.

(I.19) Commodity code (HS code)

Enter the appropriate Harmonized System (HS) codes of the World Customs Organization for the products in the shipment. The exporter should work with the importer to confirm that the appropriate code is used. A list of HS codes for dairy products can be found in [Exhibit 1.D](#) attached to this document.

Note: some EU member states only allow one HS code per certificate, it is the exporter's responsibility to work with their importer to confirm if multiple HS codes are allowed on one certificate.

(I.20) Quantity

Enter both the Gross and Net Weight of the consignment in metric units. The EU has indicated that both are required. Gross weight is the weight including the packaging. The EU has indicated that the Shipping container weight does not have to be included. Net weight is the weight of the materials shipped not including packaging. **Only METRIC units (i.e., MT, KG or grams) may be used.**

(I.21) Temperature of product

Select the appropriate box for the commodity shipped.

(I.22) Number of packages

Provide the total number of packages of dairy products in the consignment.

(I.23) Identification of container/Seal number

Provide the container and seal number. Container and seal numbers (if applicable) must be included. Type N/A if shipping via air.

(I.24) Commodities certified for:

Check the box for "Human Consumption." This box must be checked by the applicant. AMS does not have authority to issue export certificates on products for animal feed. All certificates for animal feed products are issued by USDA Animal Health Protection Inspection Service (APHIS). **By checking this box the applicant is certifying that the product is being exported as and will be used for human consumption.**

(I.26) For transit through the EU to 3rd country

Check this box if consignment is being transshipped through the EU. Enter the country of final destination and the appropriate ISO code for the country of final destination. See Box I.27 for those shipments where the final destination is a country in the EU.

(I.27) For Import or admission into the EU

Check this box for those shipments that are destined for an EU country as their final destination.

(I.28) Identification of commodities

Species

Provide the species (Scientific name) from which the milk was obtained to make the product. The scientific name for cows is Bovine; for sheep is Ovine; and for goats is Caprine.

Approval number of establishment manufacturing plant

Provide the approval number of the establishment approved to export to the EU. This is the approval number from the first column of the [Dairy Plant Reference](#) list. A maximum of three plants may be included on one certificate. Each plant should be listed on a single line.

Number of packages

Enter the total number of packages in the consignment from each approved plant.

Net weight

Enter the total net weight of the product from each approved plant. **Only METRIC units (i.e., MT, KG or grams) may be used.**

Batch number

Provide all the batch numbers from each plant that are in this consignment. If the batch codes don't fit in the space allowed, the additional two fields below can be used.

Exhibit 1.A

EU Health Certificate Worksheet

| | |
|--|-------------------------------------|
| Applicant (Company Name) | Mail Certificate to |
| Applicant Number | Contact |
| Customer Ref | Company |
| Contact | Street |
| E-Mail Address | City |
| Telephone | State |
| Fax <input type="checkbox"/> Faxed Certificate* | Zip Additional Certified Copies* |

*additional charges apply

| | | | | | | |
|---|----------|--|---|----------------------------|----------|------|
| I.1 Consignor Name | | I.2 Certificate reference number | | I.2.a | | |
| Address | | I.3 Central Competent Authority AMS | | | | |
| Tel.N° | | I.4 Local competent Authority | | | | |
| I.5 Consignee Name | | I.6 | | | | |
| Address | | | | | | |
| Postal code | | | | | | |
| Tel.N° | | | | | | |
| I.7 Country of origin | ISO code | I.8 Region of origin | Code | I.9 Country of destination | ISO code | I.10 |
| I.11 Place of origin Name | | Approval number | | I.12 | | |
| Address | | | | | | |
| I.13 Place of loading | | I.14 Date of departure | | | | |
| I.15 Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Road vehicle <input type="checkbox"/> | | Railway wagon <input type="checkbox"/> | | I.16 Entry BIP in EU | | |
| Identification: Documentation reference: | | I.17 | | | | |
| I.18 Description of commodity | | | I.19 Commodity code (HS code) | | | |
| | | | I.20 Quantity (Net/Gross Weight) | | | |
| I.21 Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/> | | I.22 Number of packages | | | | |
| I.23 Identification of container/Seal number | | I.24 Type of packaging | | | | |
| I.25 Commodities certified for: Human consumption <input type="checkbox"/> | | | | | | |
| I.26 For transit through EU to 3 rd country 3 rd country ISO code <input type="checkbox"/> | | | I.27 For import or admission into EU <input type="checkbox"/> | | | |
| I.28 Identification of the commodities Species (Scientific name) Approval number of establishment manufacturing plant Number of packages Net weight Batch number | | | | | | |

Exhibit 1.B.1

(This Certificate of Conformance must be provided with each request for health certificates issued by the Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service, United States Department of Agriculture, for shipment to the EU. **The Certificate of Conformance shall be provided on company letterhead that includes company name, address, 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 European Union Certification:

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 (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.

The signer of this Certificate of Conformance acknowledges sole responsibility for maintaining adequate records to trace the production and Certificates of Conformance for all dairy products or ingredient use in the products presented for certification. Failure to maintain such records will cause ineligibility to receive certifications to the European Union.

Signature and title of individual providing certification

Date

PRODUCT NAME, LOT NUMBERS AND MANUFACTURING DATES COVERED BY THIS CERTIFICATE OF CONFORMANCE ARE LISTED BELOW:

Exhibit 1.B.2

(This Certificate of Conformance must be provided with each consignment of dairy products for which a health certificate for shipment to the EU will be requested from the Dairy Grading Branch, AMS. **The Certificate of Conformance shall be provided on company letterhead that includes company name, address, 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 Dairy Ingredients and/or 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 (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.

The signer of this Certificate of Conformance acknowledges sole responsibility for maintaining adequate records to trace the production and Certificates of Conformance for all dairy products or ingredient use in the products covered by this certificate. Failure to maintain such records will cause ineligibility to receive certifications to the European Union.

Signature and title of individual providing certification

Date

PRODUCT NAME, LOT NUMBERS AND MANUFACTURING DATES (MONTH) COVERED BY THIS CERTIFICATE OF CONFORMANCE ARE LISTED BELOW:

Exhibit1.B.3

(This Certificate of Conformance must be provided by suppliers with each shipment of dairy ingredients used in product manufactured for shipment to the EU. **The Certificate of Conformance shall be provided on company letterhead that includes company name, address and phone number.** This Certificate of Conformance shall be signed and dated by the supplier for each shipment of product; “blanket certificates” are not acceptable. All lot numbers must be traceable to the production records of product certified by Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service, United States Department of Agriculture for shipment to the EU.)

Certificate of Conformance

Milk Supplier:

I hereby certify that the milk products included in the attached manifest were produced from raw milk meeting the somatic cell (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.

Signature and title of individual providing certification

Date

PRODUCT NAME, LOT NUMBERS AND MANUFACTURING DATES COVERED BY THIS CERTIFICATE OF CONFORMANCE ARE LISTED BELOW:

Border Inspection Posts (BIP) in the European Union

| Country | Port Name | Port Code | Type | Comments |
|----------------|----------------------------|-----------|---------|-------------|
| AUSTRIA | Linz | AT LNZ 4 | Airport | |
| AUSTRIA | WienSchwechat | AT VIE 4 | Airport | Vienna |
| BELGIUM | Antwerpen | BE ANR 1 | Port | Antwerp |
| BELGIUM | BrusselZaventem | BE BRU 4 | Airport | Brussels |
| BELGIUM | Liege | BE LGG 4 | Airport | |
| BELGIUM | Zeebrugge | BE ZEE 1 | Port | |
| BULGARIA | Burgas | BG BOJ 1 | Port | |
| BULGARIA | Sofia | BG SOF 4 | Airport | |
| BULGARIA | Varna | BG VAR 1 | Port | |
| CYPRUS | Larnaka | CY LCA 4 | Airport | |
| CYPRUS | Limassol | CY LMS 1 | Port | |
| CZECH REPUBLIC | Prague Ruzyne | CZ PRG 4 | Airport | Prague |
| DENMARK | Aalborg 1 (Greenland Port) | DK AAL 1a | Port | Aalborg |
| DENMARK | Aalborg 2 (Greenland Port) | DK AAL 1b | Port | Aalborg |
| DENMARK | Aarhus | DK AAR 1 | Port | Aarhus |
| DENMARK | Esbjerg | DK EBJ 1 | Port | |
| DENMARK | Fredericia | DK FRC 1 | Port | |
| DENMARK | Hirtshals | DK HIR 1 | Port | |
| DENMARK | Billund | DK BLL 4 | Airport | |
| DENMARK | Kobenhavn | DK CPH 4 | Airport | Copenhagen |
| DENMARK | Skagen | DK SKA 1 | Port | |
| ESTONIA | Muuga | EE MUG 1 | Port | |
| ESTONIA | Paldiski | EE PLS 1 | Port | |
| FINLAND | Hamina | FI HMN 1 | Port | |
| FINLAND | Helsinki | FI HEL 4 | Airport | |
| FINLAND | Helsinki | FI HEL 1 | Port | |
| FRANCE | Bordeaux | FR BOD 4 | Airport | |
| FRANCE | Bordeaux | FR BOD 1 | Port | |
| FRANCE | Brest | FR BES 1 | Port | |
| FRANCE | Châteauroux-Déols | FR CHR 4 | Airport | Châteauroux |
| FRANCE | Dunkerque | FR DKK 1 | Port | Dunkirk |
| FRANCE | Le Havre | FR LEH 1 | Port | |
| FRANCE | Lyon-Saint Exupéry | FR LIO 4 | Airport | Lyon |
| FRANCE | Marseille Port (15) | FR MRS 1 | Port | Marseille |
| FRANCE | Marseille Fos-sur-Mer | FR FOS 1 | Port | Marseille |
| FRANCE | Marseille Airport | FR MRS 4 | Airport | Marseille |
| FRANCE | Nantes Saint-Nazaire | FR NTE 1 | Port | Nantes |
| FRANCE | Nice | FR NCE 4 | Airport | |
| FRANCE | Orly | FR ORY 4 | Airport | Paris |
| FRANCE | Roissy Charles-de-Gaulle | FR CDG 4 | Airport | Paris |

| Country | Port Name | Port Code | Type | Comments |
|---------|---|-----------|---------|------------------------|
| FRANCE | Rouen | FR URO 1 | Port | |
| FRANCE | Sete | FR SET 1 | Port | |
| FRANCE | Toulouse-Blagnac | FR TLS 4 | Airport | Toulouse |
| FRANCE | Vatry | FR VRY 4 | Airport | |
| GERMANY | BerlinTegel | DE TXL 4 | Airport | Berlin |
| GERMANY | Bremen | DE BRE 1 | Port | |
| GERMANY | Bremerhaven | DE BRV 1 | Port | |
| GERMANY | Dusseldorf | DE DUS 4 | Airport | |
| GERMANY | Frankfurt/Main | DE FRA 4 | Airport | Frankfurt |
| GERMANY | Hahn Airport | DE HNH 4 | Airport | Frankfurt |
| GERMANY | Hamburg Airport | DE HAM 4 | Airport | Hamburg |
| GERMANY | Hamburg Hafen | DE HAM 1 | Port | Hamburg |
| GERMANY | Hannover-Langenhagen | DE HAJ 4 | Airport | Langenhagen |
| GERMANY | Jade-Weser-Port Wilhelmshaven | DE WVN 1 | Port | |
| GERMANY | Köln | DE CGN 4 | Airport | Cologne |
| GERMANY | Leipzig-Halle | DE LEJ 4 | Airport | Schkeuditz |
| GERMANY | München | DE MUC 4 | Airport | Munich |
| GERMANY | Schönefeld | DE SXF 4 | Airport | Berlin |
| GERMANY | Stuttgart | DE STR 4 | Airport | |
| GREECE | Astakos | GR AST 1 | Port | |
| GREECE | Athens International Airport | GR ATH 4 | Airport | Athens |
| GREECE | Pireas Port | GR PIR 1 | Port | Pireaus |
| GREECE | Thessaloniki | GR SKG 4 | Airport | |
| GREECE | Thessaloniki | GR SKG 1 | Port | |
| HUNGARY | Budapest-Liszt Ferenc Nemzetközi Repülőtér | HU BUD 4 | Airport | Budapest |
| IRELAND | Port Dublin | IE DUB 1 | Port | Dublin |
| IRELAND | Shannon | IE SNN 4 | Airport | Shannon (County Clare) |
| ITALY | Ancona | IT AOI 1 | Port | |
| ITALY | Bari | IT BRI 1 | Port | |
| ITALY | Bergamo | IT BGO 4 | Airport | |
| ITALY | Bologna-Borgo Panigale | IT BLQ 4 | Airport | Bologna |
| ITALY | Civitavecchia | IT CVV 1 | Port | Rome |
| ITALY | Genova | IT GOA 1 | Port | |
| ITALY | Gioia Tauro | IT GIT 1 | Port | |
| ITALY | La Spezia | IT SPE 1 | Port | |
| ITALY | Livorno-Pisa | IT LIV 1 | Port | Livorno |
| ITALY | Livorno-Pisa | IT PSA 4 | Airport | Livorno |
| ITALY | Milano-Malpensa | IT MXP 4 | Airport | Milan |
| ITALY | Napoli | IT NAP 1 | Port | |
| ITALY | Palermo | IT PMO 1 | Port | |
| ITALY | Ravenna | IT RAN 1 | Port | |
| ITALY | Roma-Fiumicino | IT FCO 4 | Airport | Rome |
| ITALY | Salerno | IT SAL 1 | Port | |

| Country | Port Name | Port Code | Type | Comments |
|-------------|------------------------|-----------|---------|-----------------|
| ITALY | Taranto | IT TAR 1 | Port | |
| ITALY | Torino-Caselle | IT CTI 4 | Airport | Torino |
| ITALY | Trapani | IT TPS 1 | Port | |
| ITALY | Trieste | IT TRS 1 | Port | |
| ITALY | Venezia | IT VCE 4 | Airport | |
| ITALY | Venezia | IT VCE 1 | Port | |
| ITALY | Vado Ligure Savona | IT VDL 1 | Port | Vado Ligure |
| LATVIA | Riga (Riga Port) | LV RIX 1a | Port | Riga |
| LATVIA | Riga (BFT) | LV RIX 1b | Port | Riga |
| LATVIA | Ventspils | LV VNT 1 | Port | |
| LITHUANIA | Molo | LT MOM 1 | Port | |
| LITHUANIA | Malku ilankos | LT MLM 1 | Port | |
| LITHUANIA | Pilies | LT PLM 1 | Port | |
| LITHUANIA | Vilnius | LT VNO 4 | Airport | |
| LUXEMBOURG | Luxembourg | LU LUX 4 | Airport | |
| MALTA | Luqa | MT LUQ 4 | Airport | |
| MALTA | Marsaxxlok | MT MAR 1 | Port | |
| NETHERLANDS | Amsterdam | NL AMS 4 | Airport | |
| NETHERLANDS | Amsterdam | NL AMS 1 | Port | |
| NETHERLANDS | Eemshaven Port | NL EEM 1 | Port | Groningen |
| NETHERLANDS | Harlingen | NL HAR 1 | Port | |
| NETHERLANDS | Maastricht | NL MST 4 | Airport | |
| NETHERLANDS | Rotterdam | NL RTM 1 | Port | |
| NETHERLANDS | Vlissingen | NL VLI 1 | Port | Flushing |
| NORWAY | Borg | NO BRG 1 | Port | |
| NORWAY | Larvik | NO LAR 1 | Port | |
| NORWAY | Oslo | NO OSL 4 | Airport | |
| NORWAY | Oslo | NO OSL1 | Port | |
| POLAND | Gdansk | PL GDN 1 | Port | |
| POLAND | Gdynia | PL GDY 1 | Port | |
| POLAND | Swinoujscie | PL SWI 1 | Port | |
| POLAND | Szczecin | PL SZZ 1 | Port | |
| POLAND | Warszawa Okecie | PL WAW 4 | Airport | Warsaw |
| PORTUGAL | Faro | PT FAO 4 | Airport | |
| PORTUGAL | Funchal (Madeira) | PT FNC 4 | Airport | Funchal/Madeira |
| PORTUGAL | Canical (Madeira) | PT CNL 1 | Port | Madeira |
| PORTUGAL | Lisboa | PT LIS 4 | Airport | Lisbon |
| PORTUGAL | Lisboa | PT LIS 1 | Port | Lisbon |
| PORTUGAL | Porto | PT OPO 4 | Airport | |
| PORTUGAL | Porto | PT OPO 1 | Port | |
| PORTUGAL | Sines | PT SIE 1 | Port | |
| ROMANIA | Bucharest Henri Coanda | RO OTP 4 | Airport | Bucharest |
| ROMANIA | Constanta North | RO CSN 1 | Port | Constanta |
| ROMANIA | Constanta South Agiea | RO CSA 1 | Port | Constanta |

| Country | Port Name | Port Code | Type | Comments |
|----------------------------|-------------------------------|-----------|---------|----------------------------------|
| SLOVAKIA (Slovak Republic) | Bratislava | SK BTS 4 | Airport | |
| SLOVENIA | Koper | SI KOP 1 | Port | |
| SLOVENIA | Ljubljana Brnik | SI LJU 4 | Airport | Ljubljana |
| SPAIN | A CoruñaLaxe | ES LCG 1 | Port | |
| SPAIN | Algeciras | ES ALG 1 | Port | |
| SPAIN | Alicante | ES ALC 4 | Airport | |
| SPAIN | Alicante | ES ALC 1 | Port | |
| SPAIN | Almeria | ES LEI 4 | Airport | |
| SPAIN | Almeria | ES LEI 1 | Port | |
| SPAIN | Barcelona | ES BCN 4 | Airport | |
| SPAIN | Barcelona | ES BCN 1 | Port | |
| SPAIN | Bilbao | ES BIO 4 | Airport | |
| SPAIN | Bilbao | ES BIO 1 | Port | |
| SPAIN | Cadiz | ES CAD 1 | Port | |
| SPAIN | Cartagena | ES CAR 1 | Port | |
| SPAIN | Castellón | ES CAS 1 | Port | Castellón de la Plana |
| SPAIN | Ciudad Real | ES CQM 4 | Airport | |
| SPAIN | Gerona | ES GRO 4 | Airport | Girona |
| SPAIN | Gijon | ES GIJ 1 | Port | |
| SPAIN | Gran Canaria | ES LPA 4 | Airport | Canary Islands |
| SPAIN | Huelva | ES HUV 1 | Port | |
| SPAIN | Las Palmas de Gran Canaria | ES LPA 1 | Port | Las Palmas (Canary Islands) |
| SPAIN | Madrid | ES MAD 4 | Airport | |
| SPAIN | Málaga | ES AGP 4 | Airport | |
| SPAIN | Málaga | ES AGP 1 | Port | |
| SPAIN | Marín | ES MAR 1 | Port | |
| SPAIN | Palma de Mallorca (Majorca) | ES PMI 4 | Airport | Palma |
| SPAIN | Santa Cruz de Tenerife | ES SCT 1 | Port | Santa Cruz de Tenerife |
| SPAIN | Santander | ES SDR 4 | Airport | Cantabria |
| SPAIN | Santander | ES SDR 1 | Port | |
| SPAIN | Santiago de Compostela | ES SCQ 4 | Airport | Galicia |
| SPAIN | Sevilla | ES SVQ 4 | Airport | |
| SPAIN | Sevilla | ES SVQ 1 | Port | |
| SPAIN | Tarragona | ES TAR 1 | Port | |
| SPAIN | Tenerife Sur | ES TFS 4 | Airport | Tenerife Island (Canary Islands) |
| SPAIN | Valencia | ES VLC 4 | Airport | |
| SPAIN | Valencia | ES VLC 1 | Port | |
| SPAIN | Vigo | ES VGO 4 | Airport | |
| SPAIN | Vigo | ES VGO 1 | Port | |
| SPAIN | Villagarcía-Ribeira-Caramiñal | ES RIB 1 | Port | Villagarcia |
| SPAIN | Vitoria-Gasteiz | ES VIT 4 | Airport | |
| SPAIN | Zaragoza | ES ZAZ 4 | Airport | |
| SWEDEN | Goteborg | SE GOT 1 | Port | |

| Country | Port Name | Port Code | Type | Comments |
|----------------|-----------------------------|------------------|-------------|-----------------|
| SWEDEN | Goteborg-Landvetter Airport | SE GOT 4 | Airport | Landvetter |
| SWEDEN | Helsingborg | SE HEL 1 | Port | |
| SWEDEN | Stockholm | SE STO 1 | Port | |
| SWEDEN | Stockholm-Arlanda | SE ARN 4 | Airport | Stockholm |
| SWITZERLAND | Geneva | CH GVA 4 | Airport | |
| SWITZERLAND | Zurich | CH ZRH 4 | Airport | |
| UNITED KINGDOM | Belfast | GB BEL 4 | Airport | |
| UNITED KINGDOM | East Midlands | GB EMA 4 | Airport | |
| UNITED KINGDOM | Gatwick | GB LGW 4 | Airport | London |
| UNITED KINGDOM | Heathrow | GB LHR 4 | Airport | London |
| UNITED KINGDOM | Liverpool | GB LIV 1 | Port | |
| UNITED KINGDOM | Manchester | GB MNC 4 | Airport | |
| UNITED KINGDOM | Peterhead | GB PHD 1 | Port | |
| UNITED KINGDOM | Stansted | GB STN 4 | Airport | London |
| UNITED KINGDOM | Thamesport | GB THP 1 | Port | |

Exhibit 1.D

Harmonized System (HS) code for Dairy Products

*Note: To obtain an AMS Dairy Health Export Certificate the foodstuff must contain at least 10 percent dairy ingredients.

| Code | Description |
|------|--|
| 0401 | milk and cream, not concentrated or sweetened |
| 0402 | milk and cream, concentrated or sweetened |
| 0403 | buttermilk, yogurt, kephir etc, flavored etc or not |
| 0404 | whey & milk products nesoi, flavored etc. or not |
| 0405 | butter and other fats and oils derived from milk |
| 0406 | cheese and curd |
| 1702 | Other sugars, including chemically pure lactose, maltose, glucose and fructose, in solid form; sugar syrups not containing added flavouring or colouring matter; artificial honey, whether or not mixed with natural honey; caramel |
| 1806 | Chocolate and other food preparations containing cocoa |
| 1901 | Malt extract; food preparations of flour, groats, meal, starch or malt extract, not containing cocoa or containing less than 40% by weight of cocoa calculated on a totally defatted basis, not elsewhere specified or included; food preparations of goods of headings 0401 to 0404, not containing cocoa or containing less than 5% by weight of cocoa calculated on a totally defatted basis, not elsewhere specified or included |
| 1905 | Bread, pastry, cakes, biscuits and other bakers' wares, whether or not containing cocoa; communion wafers, empty cachets of a kind suitable for pharmaceutical use, sealing wafers, rice paper and similar products |
| 2101 | Extracts, essences and concentrates, of coffee, tea or maté and preparations with a basis of these products or with a basis of coffee, tea or maté; roasted chicory and other roasted coffee substitutes, and extracts, essences and concentrates thereof |
| 2103 | Sauces and preparations therefor; mixed condiments and mixed seasonings; mustard flour and meal and prepared mustard |
| 2104 | Soups and broths and preparations therefor; homogenized composite food preparations |
| 2105 | Ice cream and other edible ice, whether or not containing cocoa |
| 2106 | Food preparations not elsewhere specified or included |
| 2202 | Waters, including mineral waters and aerated waters, containing added sugar or other sweetening matter or flavoured, and other non-alcoholic beverages, not including fruit or vegetable juices of heading 2009 |
| 3501 | Casein, caseinates and other casein derivatives; casein glues |
| 3502 | Albumins (including concentrates of two or more whey proteins, containing by weight more than 80% whey proteins, calculated on the dry matter), albuminates and other albumin derivatives |
| 3504 | Peptones and their derivatives; other protein substances and their derivatives, not elsewhere specified or included; hide powder, whether or not chromed |

EXHIBIT 2

Health Certificate for dairy products derived from milk of cows, ewes, goats and buffaloes for human consumption from third countries or parts thereof authorised in column B of Annex I to Regulation (EU) No 605/2010 intended for importation into the European Union

| COUNTRY | | Veterinary certificate to EU | | | | | |
|--|--|---|---------------------------------|-------------------------------|----------------------------|----------|------|
| Part I. Details of dispatched consignment | I.1 Consignor Name | | I.2 Certificate reference No | I.2.a | | | |
| | Address | | I.3 Central competent authority | | | | |
| | Tel. | | I.4 Local competent authority | | | | |
| | I.5 Consignee Name | | I.6 | | | | |
| | Address | | | | | | |
| | Postcode | | | | | | |
| | Tel. | | | | | | |
| | I.7 Country of Origin | ISO code | I.8 Region of Origin | Code | I.9 Country of Destination | ISO Code | I.10 |
| | I.11 Place of origin Name | | Approval Number | | I.12 | | |
| | Address | | | | | | |
| | I.13 Place of loading | | I.14 Date of departure | | | | |
| | I.15 Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> | | I.16 Entry BIP in EU | | | | |
| | Identification: Documentation references: | | I.17 | | | | |
| | I.18 Description of commodity | | | I.19 Commodity code (HS code) | | | |
| | | | I.20 Quantity | | | | |
| I.21 Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/> | | | I.22 Number of packages | | | | |
| I.23 Seal/Container number | | | I.24 Type of packaging | | | | |
| I.25 Commodities certified for: Human consumption <input type="checkbox"/> | | | | | | | |
| I.26 | | I.27 For import or admission into EU <input type="checkbox"/> | | | | | |
| I.28 Identification of the commodities Manufacturing plant Number of packages Species (Scientific name) Net weight Batch number | | | | | | | |

| | | | | | | | | |
|---|-----------------------------------|------|---------------------------|-------------------------|------|-----------|-------|--|
| II. Health information | II.a Certificate reference number | II.b | | | | | | |
| <p>II.1 Animal Health Attestation</p> <p>I, the undersigned official veterinarian, declare that I am aware of the relevant provisions of Directive 2002/99/EC and of Regulation (EC) No 853/2004 and hereby certify that the dairy product described above:</p> <p>(a) has been obtained from animals:</p> <ul style="list-style-type: none"> (i) under the control of the official veterinary service, (ii) which were in a country or part thereof that has been free of foot-and-mouth disease and of rinderpest for a period of at least 12 months prior to the date of this certificate, and where vaccination against foot-and-mouth disease has not been carried out during that period, (iii) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest, and, (iv) subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 and in Directive 2002/99/EC. <p>(b) Has undergone or been produced from raw milk which has been submitted to a pasteurization treatment involving a single heat treatment with a heating effect at least equivalent to that achieved by a pasteurization process of at least 72°C for at least 15 seconds and where applicable, sufficient to ensure a negative reaction to an alkaline phosphatase test applied immediately after the heat treatment.</p> <p>II.2 Public Health Attestation</p> <p>I, the undersigned official inspector, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and hereby certify that the dairy product described above was produced in accordance with those provisions, in particular that:</p> <p>(a) it was manufactured from raw milk:</p> <ul style="list-style-type: none"> (i) which comes from holdings registered in accordance with Regulation (EC) No 852/2004 and checked in accordance with Annex IV to Regulation (EC) No 854/2004, (ii) which was produced, collected, cooled, stored and transported in accordance with the hygiene conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004, (iii) which meets the plate and somatic cell count criteria laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004, (iv) which complies with the guarantees on the residues status of raw milk provided by the monitoring plans for the detection of residues or substances submitted in accordance with Council Directive 96/23/EC, and in particular, Article 29 thereof, (v) which, pursuant to testing for residues of antibacterial drugs carried out by the food business operator in accordance with the requirements of Annex III, Section IX, Chapter I, Part III, point 4 of Regulation (EC) No 853/2004, it complies with the maximum residue limits for residues of antibacterial veterinary medicinal products laid down in the Annex to Regulation (EU) No 37/2010, (vi) which has been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005, and maximum levels for contaminants laid down in Regulation (EC) No 1881/2006. <p>(b) it comes from an establishment implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;</p> <p>(c) it has been processed, stored, wrapped, packaged and transported in accordance with the relevant hygiene conditions laid down in Annex II to Regulation (EC) No 852/2004 and Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004;</p> <p>(d) it meets the relevant criteria laid down in Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004 and the relevant microbiological criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria in foodstuffs;</p> <p>(e) the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled.</p> <p>Notes</p> <p>This certificate is intended for dairy products for human consumption from third countries or parts thereof authorized in column B of Annex I of Regulation (EU) No 605/2010 intended for importation into the European Union.</p> <p>Part I:</p> <ul style="list-style-type: none"> • Box reference I.7: Provide name and ISO code of the country or part thereof as appearing in Annex I to Regulation (EU) No 605/2010. • Box reference I.11: Name, address and approval number of establishment of dispatch. • Box reference I.15: Registration number (railway wagons or container and road vehicles), flight number (aircraft) or name (ship). In the case of transport in containers, the total number of containers and their registration number and where there is a serial number of the seal it must be indicated in box I.23. In case of unloading and reloading, the consignor must inform the border inspection post of introduction into the European Union. • Box reference I.19: Use the appropriate Harmonised System (HS) code under the following headings: 04.01; 04.02; 04.03; 04.04; 04.05; 04.06; 17.02; 21.05; 22.02; 35.01; 35.02 or 35.04. • Box reference I.20: Indicate total gross weight and total net weight. • Box reference I.23: For containers or boxes, the container number and the seal number (if applicable) should be included. • Box reference I.28: Manufacturing plant: introduce the approval number of the treatment and/or processing establishment(s) approved for export to the European Union. <p>Part II:</p> <ul style="list-style-type: none"> • The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark. | | | | | | | | |
| <p>Official veterinarian</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border-top: 1px solid black; border-bottom: 1px solid black; text-align: center;">Name (in capital letters)</td> <td style="width: 50%; border-top: 1px solid black; border-bottom: 1px solid black; text-align: center;">Qualification and title</td> </tr> <tr> <td style="border-top: 1px solid black; border-bottom: 1px solid black; text-align: center;">Date</td> <td style="border-top: 1px solid black; border-bottom: 1px solid black; text-align: center;">Signature</td> </tr> <tr> <td style="border-top: 1px solid black; border-bottom: 1px solid black; text-align: center;">Stamp</td> <td></td> </tr> </table> | | | Name (in capital letters) | Qualification and title | Date | Signature | Stamp | |
| Name (in capital letters) | Qualification and title | | | | | | | |
| Date | Signature | | | | | | | |
| Stamp | | | | | | | | |

EXHIBIT 3

Animal Health Certificate for raw milk or dairy products for human consumption, for transit⁽¹⁾⁽²⁾ in the European Union

COUNTRY

Veterinary certificate to EU

| | | | | | | | |
|---|-------------------------|--------------------|--|----------------------------------|----------------------------|-----------------|--------------------------|
| Part I. Details of dispatched consignment | I.1 Consignor Name | | I.2 Certificate reference number | | I.2.a | | |
| | Address | | I.3 Central Competent Authority | | | | |
| | Tel. | | I.4 Local competent Authority | | | | |
| | I.5 Consignee Name | | I.6 Person responsible for the load in EU Name | | | | |
| | Address | | Address | | | | |
| | Postcode | | Postcode | | | | |
| | Tel. | | Tel. | | | | |
| | I.7 Country of Origin | ISO code | I.8 Region of Origin | Code | I.9 Country of Destination | ISO Code | I.10 |
| | I.11 Place of Origin | | | I.12 Place of Destination | | | |
| | Name | | Approval Number | Customs warehouse | <input type="checkbox"/> | Ship Supplier | <input type="checkbox"/> |
| | Address | | | Name | | Approval Number | |
| | I.13 Place of loading | | I.14 Date of departure | | | | |
| | I.15 Means of transport | | | I.16 Entry BIP in EU | | | |
| Aeroplane <input type="checkbox"/> | | | Ship <input type="checkbox"/> | | | | |
| Road vehicle <input type="checkbox"/> | | | Railway wagon <input type="checkbox"/> | | | | |
| Other <input type="checkbox"/> | | | I.17 | | | | |
| I.18 Description of commodity | | | | I.19 Commodity code (HS code) | | | |
| | | | | I.20 Quantity | | | |
| I.21 Temperature of product | | | | I.22 Number of packages | | | |
| Ambient <input type="checkbox"/> | | | | Chilled <input type="checkbox"/> | | | |
| | | | | Frozen <input type="checkbox"/> | | | |
| I.23 Identification of container/Seal number | | | | I.24 Type of packaging | | | |
| I.25 Commodities certified for: | | | | | | | |
| Human consumption <input type="checkbox"/> | | | | | | | |
| I.26. For transit through EU to 3 rd Country | | | I.27. | | | | |
| 3 rd Country | | | ISO Code | | | | |
| I.28 Identification of the commodities | | | | | | | |
| Manufacturing plant | | Number of packages | | Species | | | |
| | | | | (Scientific name) | | | |
| | | | | Net weight | | | |
| | | | | Batch number | | | |

| | | |
|------------------------|-----------------------------------|------|
| II. Health information | II.a Certificate reference number | II.b |
|------------------------|-----------------------------------|------|

Part II: Certification

II.1 Animal Health Attestation

I, the undersigned official veterinarian, hereby certify that the dairy products⁽¹⁾⁽²⁾ for transit⁽²⁾ in the European Union described above:

- (a) come from a country or part thereof authorised for imports to the European Union of raw milk or dairy products as laid down in Annex I to Regulation (EU) No 605/2010,
- (b) comply with the relevant animal health conditions for the products concerned as laid down in the animal health attestation in Part II.1 of the model certificates Milk-HTB⁽²⁾ in Part 2 of Annex II to Regulation (EU) No 605/2010;
- (c) was produced on or between and⁽³⁾.

Notes

Part I:

- Box reference I.7: Provide the country and ISO code of the country or part thereof as appearing in Annex I to Regulation (EU) No 605/2010.
- Box reference I.11: Name, address and approval number of establishments of dispatch. Name of the country of origin which must be the same as the country of export.
- Box reference I.15: Registration number (railway wagons or container and road vehicle), flight number (aircraft) or name (ship). In the case of transport in containers, the total number of containers and their registration number and where there is a serial number of the seal it must be indicated in box I.23. In case of unloading and reloading, the consignor must inform the border inspection post of introduction into the European Union.
- Box reference I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation: 04.01; 04.02; 04.03; 04.04; 04.05; 04.06; 17.02; 19.01; 21.05; 21.06.90.98; 22.02; 35.01; 35.02; or 35.04.
- Box reference I.20: Indicate total gross weight and total net weight.
- Box reference I.23: for containers or boxes, the container number and the seal number (if applicable) should be included.
- Box reference I.28: manufacturing plant: introduce the approval number of the production holding(s), collection centre or standardization centre approved for exportation to the European Union.

Part II:

- ⁽¹⁾ Raw milk and dairy products means, raw milk and dairy products for human consumption in transit or storage in accordance with Article 12(4) or Article 13 of Council Directive 97/78/EC.
- ⁽²⁾ Keep as appropriate.
- ⁽³⁾ Date or dates of production. Imports of raw milk and dairy products shall not be allowed when obtained either prior to the date of authorisation for exportation to the European Union of the third country or part thereof mentioned under I.7 and I.8, or during a period where restrictive measures have been adopted by the European Union against imports of raw milk and dairy products from this third country or part thereof.
- The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

Official veterinarian

| | |
|---|---|
| <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Name (in capital letters) | <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Qualification and title |
| <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Date | |
| <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Stamp | <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Signature |