COMMISSION DECISION
of 29 April 2004
laying down animal and public health and veterinary certifications conditions for introduction in
the Community of heat-treated milk, milk-based products and raw milk intended for human
consumption
(notified under document number C(2004) 1691)
(Text with EEA relevance)
(2004/438/EC)
(OJ L 189, 27.5.2004, p. 57)

Amended by:


Corrected by:

COMMISSION DECISION
of 29 April 2004
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(notified under document number C(2004) 1691)
(Text with EEA relevance)
(2004/438/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat treated milk and milk-based products (1), and in particular Article 23 (2) (b) and (3) (a), (c) and (d) thereof,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (2), and in particular Article 8 (1) and (4) and Article 9 (4) (a) and (c) thereof,

Whereas:


(3) Commission Decision 95/340/EC (3) draws up a provisional list of third countries from which Member States authorise imports of milk and milk-based products.

(4) Commission Decision 95/342/EC (4) lays down the treatment to be applied to milk and milk-based products for human consumption from third countries or parts of third countries where there is a risk of foot-and-mouth disease; its provisions should be updated to take account of the treatment against the foot-and-mouth virus provided for in Council Directive 2003/85/EC (5) laying down Community measures for the control of foot-and-mouth disease.


In the interest of clarity and rationality Decisions 95/340/EC, 95/342/EC and 95/343/EC should be repealed and replaced by this Decision.

Provision should however be made to make it possible to use the format of the certificates laid down in Decision 95/343/EC for an interim period of time.

Council Directive 97/78/EC (1) lays down the principles governing the organisation of veterinary checks on products entering the Community from third countries and certain provisions for transit are already provided for in Article 11, such as the use of ANIMO messages and of the common veterinary entry document.

However, it is necessary in order to safeguard the disease situation in the Community to further ensure that consignments of milk transiting through the Community comply with the animal health import conditions applicable for authorised countries.

Council Decision 79/542/EEC of 21 December 1976 drawing up a list of third countries or parts of third countries, and laying down animal and public health and veterinary certification conditions for the importation into the Community of certain live animals and their fresh meat (2), has recently been amended to include general transit conditions and a derogation for transit between Russia with a reference to the specific border inspection posts designated for this latter purpose.

In the light of experience, it appears that the presentation to the border inspection post, pursuant to Article 7 of Directive 97/78/EC, of the original veterinary documents, established in the exporting third country to fulfil the regulatory requirement of the third country of destination, is not sufficient to ensure that the animal health conditions required for the safe introduction into the territory of the Community of the products concerned are effectively satisfied; it is therefore appropriate to establish a specific model of animal health certificate to be used in transit situations for the products concerned.

It is further appropriate to clarify the implementation of the condition laid down in Article 11 of Directive 97/78/EC, that transit is only allowed from third countries whose products are not prohibited for introduction in the territory of the Community, by making reference to the list of third countries annexed to this Decision.

However specific conditions for transits via the Community of consignments to and from Russia should be foreseen due to the geographical situation of Kaliningrad and taking into account climatic problems impeding the use of some ports at certain times of the year.

Commission Decision 2001/881/EC (3) draws up a list of border inspection posts agreed for veterinary checks on animals and animal products from third countries and it is appropriate to specify the border inspection posts designated for the control of such transits taking into account this Decision.

The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Imports into the Community of milk and milk-based products shall only be allowed if the milk and milk-based products comply with Articles 2, 3, and 5.

Transit and storage of milk and milk-based products shall only be allowed if the milk and milk-based products comply with Articles 4 and 5.

Article 2

1. Member States shall authorise imports of raw milk and raw milk-based products from third countries so authorised in column A of the list in Annex I.

2. Member States shall authorise imports of milk and milk-based products that have undergone:

   — a single heat treatment with a heating effect at least equal to that achieved by a pasteurisation process of at least 72 °C for at least 15 seconds,

   and

   — sufficient to ensure a negative reaction to a phosphatase test,

from third countries so authorised in column B of the list in Annex I where there is no threat of foot-and-mouth disease.

3. Member States shall authorise imports of milk and milk-based products that have undergone either:

   (a) a sterilisation process, to achieve an $F_0$ value equal to or greater than three,

   or

   (b) an ultra high temperature (UHT) treatment at 132 °C for at least one second,

   or

   (c) a high temperature short time pasteurisation treatment at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test (HTST) applied twice to milk with a pH equal to or above 7.0,

   or

   (d) a HTST treatment of milk with a pH below 7.0,

   or

   (e) a HTST treatment combined with another physical treatment by:

      (i) either lowering the pH below 6 for one hour,

      or

      (ii) additional heating to 72 °C or more, combined with desiccation,

from third countries so authorised in column C of the list in Annex I where there is a threat of foot-and-mouth disease. The milk-based products must either undergo one of the above treatments or be produced from milk treated in accordance with the treatments laid down above.
Article 3

1. Consignments of milk and milk-based products from third countries authorised in accordance with Article 2 shall be accompanied by, and comply with, conditions laid down in, a health certificate drawn up in accordance with the relevant model drawn up in Part 2 of Annex II to this Decision, as follows:

— ‘Milk-RM’ for raw milk intended to be accepted at a collection centre, standardisation centre, treatment establishment or processing establishment,

— ‘Milk-RMP’ for raw milk products,

— ‘Milk-HTB’ for heat-treated milk, heat-treated milk-based products and milk-based products made from heat-treated milk, coming from third countries or parts of third countries in which there is no threat of foot-and-mouth disease,

— ‘Milk-HTC’ for heat-treated milk, heat-treated milk-based products and milk-based products made from heat-treated milk coming from third countries or parts of third countries in which there is a threat of foot-and-mouth disease, however those countries already authorised for such imports (where there is no threat of foot and mouth) may use this model.

2. The health certificates shall be completed in accordance with the notes set out in Part 1 of Annex II.

Article 4

1. Consignments of milk and milk-based products, introduced into the territory of the Community and which are destined for a third country either by transit immediately or after storage in accordance with Articles 12 (4) or 13 of Directive 97/78/EC and not intended for importation into the EC, shall comply with the following requirements:

(a) they shall come from the territory of a third country or a part thereof authorised in Annex I to this Decision, according to the treatment required for the product concerned as laid down in Article 2;

(b) they shall meet the specific animal health conditions set out in section 9 of the corresponding model health certificate drawn up under Part 2 of Annex II to this Decision;

(c) they shall be accompanied by an animal health certificate established in accordance with the model laid down in Part 3 of Annex II to this Decision, signed by an official veterinarian of the competent veterinary services of the third country concerned;

(d) they are certified as acceptable for transit or storage (as appropriate) on the Common Veterinary Entry Document by the Official Veterinarian of the Border Inspection Post of introduction.

2. (a) By way of derogation from paragraph 1 above and Article 5, Member States shall authorise the transit by road or by rail through the Community, between designated Community border inspection posts listed in the Annex to Decision 2001/881/EC, of consignments coming from and destined to Russia directly or via another third country provided that the following conditions are met:

(i) the consignment shall be sealed with a serially numbered seal at the border inspection post of entry to the EC by the veterinary services of the competent authority;

(ii) the documents accompanying the consignment and referred to in Article 7 of Directive 97/78/EC shall be stamped ‘ONLY FOR TRANSIT TO RUSSIA VIA
THE EC on each page by the official veterinarian of the competent authority responsible for the border inspection post;

(iii) the procedural requirements provided for in Article 11 of Directive 97/78/EC shall be complied with;

(iv) the consignment is certified as acceptable for transit on the Common Veterinary Entry Document by the Official Veterinarian of the Border Inspection Post of introduction.

(b) Unloading or storage on EC territory of such consignments, as defined in Article 12 (4) or Article 13 respectively of Directive 97/78/EC, shall not be allowed.

(c) Regular audits shall be made by the competent authority to ensure that the number of consignments and the quantities of products leaving the EC territory matches the number and quantities entering.

Article 5

Milk and milk-based products from authorised third countries or parts of third countries where an outbreak of foot-and-mouth disease has occurred within the last 12 months or which have carried out vaccination against foot-and-mouth disease in the last 12 months shall, before they are introduced into Community territory, undergo one of the treatments listed in Article 2 (3).

Article 6

Decisions 95/340/EC, 95/342/EC and 95/343/EC are repealed.

Article 7

The certificates drawn up in the format under Decision 95/343/EC may be used until six months after the date laid down in paragraph 1 of Article 8 at the latest.

Article 8

1. This Decision shall apply from 1 May 2004.

2. Article 4(1) and Part 3 of Annex II shall only apply from 1 January 2005.

3. References made by Community legislation to the list of third countries appearing in the Annex to Decision 95/340/EC shall be construed as references to the list of third countries appearing in Annex I to this Decision.

Article 9

This Decision is addressed to the Member States.

Done at Brussels, 29 April 2004.
ANNEX I

'+': country is authorised

'0': country is not authorised

<table>
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(*) Certificates in accordance with the Agreement between the European Community and the Swiss Confederation (as last amended) on trade in agricultural products (OJ L 114, 30.4.2002, p. 132).

(**) Provisional code which does not prejudge in any way the definitive nomenclature for this Country, which is to be agreed following the conclusion of negotiations currently taking place on this subject in the United Nations.

## ANNEX II
### PART 1

#### Models of health certificates

- **Milk-RM**: for raw milk from third countries or parts of third countries included in Annex I column A intended to be accepted at a collection centre, standardisation centre, treatment establishment or processing establishment.

- **Milk-RMP**: for raw milk products from third countries or parts of third countries included in Annex I column A.

- **Milk-HTB**: for heat-treated milk, heat-treated milk-based products or milk-based products made from heat-treated milk from third countries or parts of third countries included in Annex I column B.

- **Milk-HTC**: for heat-treated milk, heat-treated milk-based products or milk-based products made from heat-treated milk from third countries or parts of third countries included in Annex I column C.

- **Milk-T/S**: for milk and milk-based products, for transit/storage in the European Community.

#### Notes

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<tr>
<td>(a)</td>
<td>Health certificates shall be produced by the exporting country, based on the models appearing in this Annex II, according to the layout of the model that corresponds to the milk and milk-based products concerned. They shall contain, in the numbered order that appears in the model, the attestations that are required for any third country and, as the case may be, those supplementary guarantees that are required for the exporting third country or part thereof.</td>
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<tr>
<td>(b)</td>
<td>The original of each certificate shall consist of a single page, both sides, or, where more text is required, it shall be in such a form that all pages needed are part of an integrated whole and indivisible.</td>
</tr>
<tr>
<td>(c)</td>
<td>It shall be drawn up in at least one of the official languages of the EU Member State in which the inspection at the border post shall be carried out and of the EU Member State of destination. However, these Member States may allow other languages, if necessary, accompanied by an official translation.</td>
</tr>
<tr>
<td>(d)</td>
<td>If for reasons of identification of the items of the consignment (schedule in point 8 of the model of certificate), additional pages are attached to the certificate, these pages shall also be considered as forming part of the original of the certificate by the application of the signature and stamp of the certifying official, in each of the pages.</td>
</tr>
<tr>
<td>(e)</td>
<td>When the certificate, including additional schedules referred to in (d), comprises more than one page, each page shall be numbered - (page number) of (total number of pages) - on its bottom and shall bear the code number of the certificate that has been designated by the competent authority on its top.</td>
</tr>
<tr>
<td>(f)</td>
<td>The original of the certificate must be completed and signed by a representative of the competent authority responsible for verifying and certifying that the raw milk, heat-treated milk or milk-based products meet the requirements of Directive 92/46/EEC.</td>
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<tr>
<td>(g)</td>
<td>The competent authorities of the exporting country shall ensure that the principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed.</td>
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<tr>
<td>(h)</td>
<td>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.</td>
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<tr>
<td>(i)</td>
<td>The original of the certificate must accompany the consignment at the EU border inspection post.</td>
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**PART 2**

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<th>HEALTH CERTIFICATE</th>
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<td>for raw milk from third countries or parts of third countries authorised in Column A of Annex I to Commission Decision 2004/438/EC intended to be accepted at a collection centre, standardisation centre, treatment establishment or processing establishment in the European Community and then to be used for human consumption:</td>
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### C1

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<th>6. Place of loading for exportation</th>
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</tbody>
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<table>
<thead>
<tr>
<th>8. Identification of the raw milk</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1. Raw milk from: ..................</td>
</tr>
<tr>
<td>..........................................................</td>
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<tr>
<td>..........................................................</td>
</tr>
<tr>
<td>..........................................................</td>
</tr>
<tr>
<td>8.2. Code number (as appropriate):</td>
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<td>..........................................................</td>
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<tr>
<td>..........................................................</td>
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<tr>
<td>..........................................................</td>
</tr>
<tr>
<td>8.3. Packaging: ..........................</td>
</tr>
<tr>
<td>..........................................................</td>
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<tr>
<td>..........................................................</td>
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<tr>
<td>..........................................................</td>
</tr>
<tr>
<td>8.4. Number of packaging units: ..........................</td>
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<td>..........................................................</td>
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<td>..........................................................</td>
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<tr>
<td>..........................................................</td>
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<tr>
<td>8.5. Net weight: ..........................</td>
</tr>
<tr>
<td>..........................................................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. Animal Health attestation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I, the undersigned official veterinarian, hereby certify:</td>
</tr>
<tr>
<td>9.1. that the raw milk described above has been obtained from animals:</td>
</tr>
<tr>
<td>a) under the control of the official veterinary service,</td>
</tr>
<tr>
<td>b) which were in a country or region that has been free of foot-and-mouth disease and of rinderpest for at least 12 months, and where vaccination against foot-and-mouth disease has not been carried out for at least 12 months,</td>
</tr>
<tr>
<td>c) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest, and,</td>
</tr>
<tr>
<td>d) subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in Annex A, Chapter I of Directive 92/46/EEC;</td>
</tr>
<tr>
<td>9.2. that I am familiar with the animal health requirements of Directive 92/46/EEC.</td>
</tr>
</tbody>
</table>

| 7.3. Consignment identification details (5): |
| .......................................................... |
| .......................................................... |
| .......................................................... |

---

**Model Milk-RM**
10. Official stamp and signature

Done at ........................................................., on ..............................................................

(stamp) (1)

..........................................................................................................................

(signature of official veterinarian) (1)

..........................................................................................................................

(name in capital letters, qualifications and title)

11. Public Health attestation

I, the undersigned official inspector, hereby certify:

11.1. that the raw milk described above:

a) does not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC, contain residues of anti-microbial substances in excess of the limits laid down in Annexes I and III to Council Regulation (EEC) No 2377/90, as amended;

b) does not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC, contain pesticide residues in excess of the maximum levels laid down in Annex II to Council Directive 86/383/EEC, as amended;

c) does not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC, contain contaminants in excess of the maximum tolerances laid down in the Community list provided for in Article 2 (3) of Council Regulation (EEC) No 315/93;

d) comes from registered and checked holdings meeting the conditions of hygiene laid down in Chapter II of Annex A to Directive 92/46/EEC;

e) was obtained, collected, cooled, stored and transported in accordance with the specific hygiene conditions laid down in Chapter III of Annex A to Directive 92/46/EEC;

f) was transported, where applicable, in tanks as described in Article 16 (2) of Directive 92/46/EEC;

g) meets the plate and somatic cell count standards laid down in Chapter IV of Annex A to Directive 92/46/EEC;

h) was collected and standardised, where necessary, in accordance with the hygiene conditions laid down in Chapters I, III and IV of Annex B to Directive 92/46/EEC;


12. Official stamp and signature

Done at ........................................................., on ..............................................................

(stamp) (1)

..........................................................................................................................

(signature of official inspector) (1)

..........................................................................................................................

(name in capital letters, qualifications and title)

Notes

(1) Issued by the competent authority.

(2) Country and ISO code of the territory as appearing in Annex I to Decision 2004/438/EC (as last amended).

(2) To be specified if the authorisation to import into the Community is restricted to certain regions of the third country concerned.

(3) Complete as appropriate.

(4) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft.

In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be indicated under point 7.3.

(5) Complete if appropriate.

(6) 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.
### Model Milk-RMP

<table>
<thead>
<tr>
<th>1. Consignor (name and address in full)</th>
<th>HEALTH CERTIFICATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>...........................................</td>
<td>for raw milk products for human consumption from third countries or parts of third countries authorised in Column A of Annex I to Commission Decision 2004/638/EC intended for consignment to the European Community</td>
</tr>
<tr>
<td>...........................................</td>
<td>No (1) ORIGINAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Consignee (name and address in full)</th>
<th>3. Origin of the raw milk products (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>...........................................</td>
<td>3.1 ISO code and name of Country (and region, where applicable) (2): .......................................................</td>
</tr>
<tr>
<td>...........................................</td>
<td>3.2 Code of territory: .......................................................</td>
</tr>
<tr>
<td>...........................................</td>
<td>3.3 Name and official approval or registration number of [production holding(s)] [collection centre] [standardisation centre] (2) approved for exportation to the Community: .......................................................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Intended destination of the raw milk products</th>
<th>4. Competent Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1 EU Member State: ..................................</td>
<td>4.1 Ministry: .................</td>
</tr>
<tr>
<td>5.2 Place of destination: ............................</td>
<td>4.2 Service: .................</td>
</tr>
<tr>
<td>..........................................................</td>
<td>4.3 Local/regional level: ..........</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Place of loading for exportation</th>
<th>7. Means of transport and consignment identification (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>...........................................</td>
<td>7.1 (Lorry)(Rail-wagon)(Ship)(Aircraft) (2)</td>
</tr>
<tr>
<td>...........................................</td>
<td>7.2 Registration number(s), ship name or flight number: .......................................................</td>
</tr>
<tr>
<td>...........................................</td>
<td>7.3 Consignment identification details (2): .......................................................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1 Raw milk from: ..................................</td>
<td>I, the undersigned official veterinarian, hereby certify:</td>
</tr>
<tr>
<td>8.2 Code number (as appropriate): .................</td>
<td>9.1 that the raw milk product described above has been manufactured from raw milk obtained from animals:</td>
</tr>
<tr>
<td>8.3 Packaging: .........................................</td>
<td>a) under the control of the official veterinary service,</td>
</tr>
<tr>
<td>8.4 Number of packaging units: ......................</td>
<td>b) which were in a country or region that has been free of foot-and-mouth disease and of rinderpest for at least 12 months, and where vaccination against foot-and-mouth disease has not been carried out for at least 12 months,</td>
</tr>
<tr>
<td>8.5 Net weight: .........................................</td>
<td>c) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest, and,</td>
</tr>
<tr>
<td>..........................................................</td>
<td>d) subject to regular veterinary inspectors inspections to ensure that they satisfy the animal health conditions laid down in Annex A, Chapter I of Directive 92/46/EEC;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>9.1 that the raw milk product described above has been manufactured from raw milk obtained from animals:</td>
<td>Done at ....................................................... on .......................................................</td>
</tr>
<tr>
<td>a) under the control of the official veterinary service,</td>
<td>....................................................... (signature of official veterinarian) (1)</td>
</tr>
<tr>
<td>b) which were in a country or region that has been free of foot-and-mouth disease and of rinderpest for at least 12 months, and where vaccination against foot-and-mouth disease has not been carried out for at least 12 months,</td>
<td>....................................................... (name in capital letters, qualifications and title)</td>
</tr>
<tr>
<td>c) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest, and,</td>
<td></td>
</tr>
<tr>
<td>d) subject to regular veterinary inspectors inspections to ensure that they satisfy the animal health conditions laid down in Annex A, Chapter I of Directive 92/46/EEC;</td>
<td></td>
</tr>
</tbody>
</table>
11. Public Health attestation

I, the undersigned official inspector, hereby certify:

11.1. that the raw milk product described above:

a) was manufactured from raw milk:
   i) not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC, containing residues of anti-microbial substances in excess of the limits laid down in Annexes I and III to Regulation (EEC) No 2377/90, as amended;
   ii) not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC, containing pesticide residues in excess of the maximum levels laid down in Annex II to Directive 86/383/EEC, as amended;
   iii) not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC, containing contaminants in excess of the maximum tolerances laid down in the Community list provided for in Article 2 (3) of Regulation (EEC) No 315/93;
   iv) which comes from registered and checked holdings meeting the hygiene conditions laid down in Chapter II of Annex A to Directive 92/46/EEC;
   v) which was obtained, collected, cooled, stored and transported in accordance with the specific hygiene conditions laid down in Chapter III of Annex A to Directive 92/46/EEC;
   vi) which meets the plate and somatic cell count standards laid down in Directive 92/46/EEC, Annex A, Chapter IV, paragraph A, point 3 as regards cow's milk, paragraph B, point 2 as regards buffalo milk, and paragraph C, point 2 as regards goat's and sheep's milk, and
   vii) which, where necessary, was collected and standardised in accordance with the hygiene conditions laid down in Chapters I, III and IV of Annex B to Directive 92/46/EEC;

b) comes from a processing establishment offering equivalent guarantees to those laid down in Chapter II of Directive 92/46/EEC shown on the list of establishments authorised to export to the European Community and which is subject to supervision by the competent authority in accordance with the provisions of Chapter VI of Annex C to Directive 92/46/EEC;

c) has not undergone any heat treatment during its manufacture from raw milk;

d) meets the relevant microbiological criteria laid down in Chapter II of Annex C to Directive 92/46/EEC;

e) has been wrapped and packaged in accordance with Chapter III of Annex C to Directive 92/46/EEC, and;


12. Official stamp and signature

Done at ................................................................. on .................................................................

(stamp) (n)

.................................................................

(signature of official inspector) (n)

.................................................................

(name in capital letters, qualifications and title)

Notes

(*) Issued by the competent authority.
(©) Country and ISO code of the territory as appearing in Annex I to Decision 2004/438/EC (as last amended).
(©) Keep as appropriate.
(©) To be specified if the authorisation to import into the Community is restricted to certain regions of the third country concerned.
(©) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft.
(©) In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be indicated under point 7.3.
(©) Complete if appropriate.
(©) 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.
### Model Milk-4HTB

#### HEALTH CERTIFICATE

for heat-treated milk, milk-based products made from heat-treated milk or heat-treated milk-based products for human consumption from third countries or parts of third countries authorised in Column B of Annex I of Commission Decision 2004/438/EC intended for consignment to the European Community

<table>
<thead>
<tr>
<th>No (1)</th>
<th>ORIGIN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. **Consignor (name and address in full)**

   ........................................................................................................................................

2. **Consignee (name and address in full)**

   ........................................................................................................................................

3. **Origin of the milk and milk-based products (2)**
   3.1. ISO code and name of Country: ...............................................................................
   3.2. Code of territory: .......................................................................................................
   3.3. Name(s) and official approval number(s) of treatment and/or processing establishment(s) approved for export to the Community

4. **Competent Authority**
   4.1. Ministry: ..................................................................................................................
   4.2. Service: .....................................................................................................................
   4.3. Local/regional level: .................................................................................................

5. **Intended destination of the milk and milk-based products**
   5.1. EU Member State: .....................................................................................................
   5.2. Place of destination: .................................................................................................

6. **Place of loading for exportation**

7. **Means of transport and consignment identification (3)**
   7.1. [Lorry][Rail-wagon][Ship][Aircraft] (4)
   7.2. Registration number(s), ship name or flight number:

8. **Identification of the milk and milk-based products**
   8.1. Milk from: ..................................................................................................................
   8.2. Code number (as appropriate): ..................................................................................
   8.3. Packaging: ..................................................................................................................
   8.4. Number of packaging units: ......................................................................................
   8.5. Net weight: ................................................................................................................

9. **Animal Health attestation**

   I, the undersigned official veterinarian, hereby certify:

   9.1. that the [heat-treated milk][milk-based product] (4) made from [heat-treated milk][heat-treated milk-based product] (4) described above has been obtained from animals:
   a) under the control of the official veterinary service,
   b) which were in a country or region that has been free of foot-and-mouth disease and of rinderpest for at least 12 months, and where vaccination against foot-and-mouth disease has not been carried out for at least 12 months,
   c) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest, and,
   d) subject to regular veterinary inspector inspections to ensure that they satisfy the animal health conditions laid down in Annex A, Chapter I of Directive 92/46/EEC, with the exception of those in paragraph 1(a)(i) and (b)(i);

   9.2. that I am familiar with the animal health requirements of Directive 92/46/EEC.

10. **Official stamp and signature**

    Done at .........................................................., on ..................................................

    ........................................................................................................................................

    (stamp) (4)

    ........................................................................................................................................

    (signature of official veterinarian) (4)

    ........................................................................................................................................

    (name in capital letters, qualifications and title)
11. Public Health attestation
I, the undersigned official inspector, hereby certify:
11.1. that the [heat-treated milk/milk-based product] (\textsuperscript{1}) made from [heat-treated milk/milk-based product] (\textsuperscript{2}) described above;
   a) was manufactured from raw milk:
      i) not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC,
         containing residues of anti-microbial substances in excess of the limits laid down in Annexes I and III to
         Regulation (EEC) No 2377/90, as amended,
      ii) not, according to the findings of monitoring plans at least equivalent to those provided for in Directive
          92/46/EEC, containing pesticide residues in excess of the maximum levels laid down in Annex III to Directive
          86/363/EEC, as amended,
      iii) not, according to the findings of monitoring plans at least equivalent to those provided for in Directive
           92/46/EEC, containing contaminants in excess of the maximum tolerances laid down in the Community
           list provided for in Article 2(3) of Regulation (EEC) No 315/93,
      iv) which comes from registered and checked holdings meeting the hygiene conditions laid down in Chapter II of
          Annex A to Directive 92/46/EEC,
   v) which was obtained, collected, cooled, stored and transported in accordance with the specific hygiene condi-
      tions laid down in Chapter III of Annex A to Directive 92/46/EEC,
   vi) which meets the plate and somatic cell count standards laid down in Chapter IV of Annex A to Directive
       92/46/EEC, and
   vii) which was collected and standardised, where necessary, in accordance with the hygiene conditions laid down
       in Chapters I, III and IV of Annex B to Directive 92/46/EEC;
   b) comes from a treatment establishment and/or processing establishment offering equivalent guarantees to those
      laid down in Chapter II of Directive 92/46/EEC shown on the list of establishments authorised to export to the
      European Community and which is subject to supervision by the competent authority in accordance with the
      provisions of Chapter VI of Annex C to Directive 92/46/EEC;
   c) has undergone heat treatment during manufacture in accordance with the specific requirements of Chapter I of
      Annex C to Directive 92/46/EEC;
   d) meets the relevant microbiological criteria laid down in Chapter II of Annex C to Directive 92/46/EEC;
   e) has been wrapped and packaged in accordance with Chapter III of Annex C to Directive 92/46/EEC;
   f) was stored and transported in accordance with the requirements of Chapter V of Annex C to Directive 92/46/EEC, and;
   g) was transported, where appropriate, in tanks as described in Article 16 (2) of Directive 92/46/EEC.
11.2. that I am aware of the provisions contained in Directive 92/46/EEC, Annexes I and III to Regulation (EEC) No 2377/90,

12. Official stamp and signature
Done at ................................................................. on .................................................................

(stamp) (\textsuperscript{1})

.................................................................

(signature of official inspector) (\textsuperscript{1})

.................................................................

(name in capital letters, qualifications and title)

Notes
\textsuperscript{(1)} Issued by the competent authority.
\textsuperscript{(2)} Country and ISO code of the territory as appearing in Annex I to Decision 2004/438/EC (as last amended).
\textsuperscript{(*)} The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the
      flight number of the aircraft.
      In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be
      indicated under point 7.3.
\textsuperscript{(*)} Keep as appropriate.
\textsuperscript{(5)} Complete if appropriate.
\textsuperscript{(*)} 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.
1. **Consignor (name and address in full)**
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

2. **Consignee (name and address in full)**
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

3. **HEALTH CERTIFICATE**

   for heat-treated milk, milk-based products made from heat-treated milk or heat-treated milk-based products for human consumption from third countries or parts of third countries authorised in Column C of Annex I to Commission Decision 2004/438/EC intended for consignment to the European Community

   No (1) ORIGINAL

   3.1. ISO code and name of Country (and region, where applicable) (1):
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   3.2. Code of territory:
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

4. **Competent Authority**

   4.1. Ministry:
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   4.2. Service:
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   4.3. Local/Regional level:
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

5. **Intended destination of the [heat-treated milk][milk-based product] from [heat-treated milk][heat-treated milk-based product] (2):**

   5.1. EU Number Status:
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   5.2. Place of destination:
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

6. **Place of loading for exportation**
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

7. **Means of trans-nd consignment identification (2)**

   7.1. [Lorry][Rail-wagon][Ship][Aircraft] (2)
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   7.2. Registration number(s), ship name or flight number: …
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………


   8.1. Milk from:
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   8.2. Description of [heat-treated milk][milk-based product] (2) made from [heat-treated milk][heat-treated milk-based product] (2):
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   8.3. Code number (as appropriate):
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   8.4. Packaging:
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   8.5. Number of packaging units:
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

   8.6. Net weight:
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

9. **Animal Health attestation**

   I, the undersigned official veterinarian, hereby certify:

9.1. That the [heat-treated milk][milk-based product] (2) made from [heat-treated milk][heat-treated milk-based product] (2) described above has been obtained from animals:

   a) under the control of the official veterinary service,
   b) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest, and,
   c) subject to regular veterinary inspectors inspections to ensure that they satisfy the animal health conditions laid down in Annex A, Chapter I of Directive 92/46/EEC;

9.2. That I am familiar with the animal health requirements of Directive 92/46/EEC.
### 10. Official stamp and signature

Done at .............................................................. on ..............................................................  

(stamp) (*)  

(signature of official veterinarian) (*)  

(name in capital letters, qualifications and title)

### 11. Public Health attestation

I, the undersigned official inspector, hereby certify:

11.1. that the [heat-treated milk][milk-based product] (*) made from [heat-treated milk][heat-treated milk-based product] (?) described above:

a) was manufactured from raw milk

i) not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/45/EEC, containing residues of anti-microbial substances in excess of the limits laid down in Annexes I and III to Regulation (EEC) No 2377/90, as amended,

ii) not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/45/EEC, containing pesticide residues in excess of the maximum levels laid down in Annex II to Directive 89/363/EEC, as amended,

iii) not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/45/EEC, containing contaminants in excess of the maximum tolerances laid down in the Community list provided for in Article 2 (3) of Regulation (EEC) No 315/93,

iv) which comes from registered and checked holdings meeting the hygiene conditions laid down in Chapter II of Annex A to Directive 92/45/EEC,

v) which was obtained, collected, cooled, stored and transported in accordance with the specific hygiene conditions laid down in Chapter III of Annex A to Directive 92/45/EEC,

vi) which meets the plate and somatic cell count standards laid down in Chapter IV of Annex A to Directive 92/45/EEC, and

vii) which was collected and standardised, where necessary, in accordance with the hygiene conditions laid down in Chapters I, III and IV of Annex B to Directive 92/45/EEC;

b) comes from a treatment establishment and/or processing establishment offering equivalent guarantees to those laid down in Chapter II of Directive 92/45/EEC shown on the list of establishments authorised to export to the European Community and which is subject to supervision by the competent authority in accordance with the provisions of Chapter VI of Annex C to Directive 92/45/EEC;

c) has undergone, prior to import into the territory of the Community:

(*) either

[i] a sterilisation process, to achieve an F0 value equal to or greater than three,

[II] an ultra high temperature (UHT) treatment at 132 °C for at least one second,

[III] a high temperature short time pasteurisation treatment at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test (HTST) applied twice to milk with a pH equal to or above 7.0,

[IV] a HTST treatment of milk with a pH below 7.0,

[V] a HTST treatment combined with another physical treatment by:

[v] lowering the pH below 6 for one hour,

[v.1] additional heating to 72 °C or more, combined with dosification;

d) meets the relevant microbiological criteria laid down in Chapter II of Annex C to Directive 92/45/EEC;

e) has been wrapped and packaged in accordance with Chapter III of Annex C to Directive 92/45/EEC;

f) was stored and transported in accordance with the requirements of Chapter V of Annex C to Directive 92/45/EEC;

g) was transported, where appropriate, in tanks as described in Article 16 (2) of Directive 92/45/EEC;


### 12. Official stamp and signature

Done at .............................................................. on ..............................................................  

(stamp) (*)  

(signature of official inspector) (*)  

(name in capital letters, qualifications and title)
Notes

(1) Issued by the competent authority.
(2) Country and ISO code of the territory as appearing in Annex I to Decision 2004/438/EC (as last amended).
(3) Keep as appropriate.
(4) To be specified if the authorisation to import into the Community is restricted to certain regions of the third country concerned.
(5) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft.
In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be indicated under point 7.3.
(6) Complete if appropriate.
(7) 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.
### ANIMAL HEALTH CERTIFICATE

for milk and milk-based products (1), for [transit](2)[storage] (3) (4) in the European Community

<table>
<thead>
<tr>
<th>No. (5)</th>
<th>ORIGINAL</th>
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#### 3. Origin of the milk and milk-based products (6)
- ISO code and name of Country: .................................................................
- Code of territory: .................................................................
- Name and official approval or registration number of [production holding(s)][collection centre][standardization centre] (7):

#### 5. Intended [transit]/[storage] (8) destination of the milk and milk-based products
- Storage in:
  - EU Member State: .................................................................
- Final third country of destination after [transit]/storage (8) (9):
  - Exit Community B/I/P name and address (10):

#### 6. Place of loading for exportation

#### 7. Means of transport and consignment identification (11)
- Lorry/(Rail-wagon)/(Ship)/(Aircraft) (11):
- Registration number(s), ship name or flight number:

#### 8. Identification of the milk and milk-based products
- Milk from: ............................................................................................. (animal species)
- Code number (as appropriate): .................................................................
- Packaging: .............................................................................................
- Number of packaging units: .....................................................................
- Net weight: .............................................................................................

#### 9. Animal Health attestation
- 1. the undersigned official veterinary, hereby certify, that the milk described above:
- 2. complies with the relevant animal health conditions for the products concerned as laid down in the animal health attestation in section 9 of the model certificates [Milk-RM]/[Milk-RMP]/[Milk-HTB]/[Milk-HTC] (12) in Part 2 of Annex II to Commission Decision 2004/438/EC;
- 3. where model certificate Milk-HTC is used, the milk has undergone the following treatment: ................................................................., as laid down in section 10.1(c) of that certificate; and
- 4. was produced on or between: ................................................................. (10).

#### 10. Official stamp and signature
- Done at .................................................................
- on .................................................................
- (stamp) (13)
- (signature of official veterinarian) (14)
- (name in capital letters, qualifications and title)
Notes

(1) Milk and milk-based products means, heat-treated milk, milk-based products and raw milk for human consumption.

(2) In accordance with Article 12 (4) or Article 13 of Council Directive 97/78/EC.

(3) Keep as appropriate.

(4) Issued by the competent authority.

(5) Country and ISO code of the territory as appearing in Annex I to Decision 2004/438/EC (as last amended).

(6) Address (and approval number if known) of the warehouse in a free zone, free warehouse, customs warehouse or ship chandler shall be included.

(7) Complete as appropriate.

(8) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft.
In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be indicated under point 7.3.

(9) Complete if appropriate.

(10) Date or dates of production. Imports of the milk and milk-based products shall not be allowed when obtained either prior to the date of authorisation for exportation to the European Community from the territory mentioned under (3), or during a period where restrictive measures have been adopted by the European Community against imports of the milk and milk-based products from this territory.

(11) 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.