COMMISSION DECISION

of 18 November 1998

concerning emergency measures made necessary by the occurrence of bovine spongiform encephalopathy in Portugal

(notified under document number C(1998) 3544)

(Text with EEA relevance)

(98/653/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market [1], as last amended by Directive 92/118/EEC [2], and in particular Article 10(4) thereof,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market [3], as last amended by Directive 92/118/EEC, and in particular Article 9(4) thereof,

(1) Whereas several distinct transmissible spongiform encephalopathies (TSEs) have been recognised for many years as occurring separately in humans and animals; whereas bovine spongiform encephalopathy (BSE) was first recognised in cattle in 1986 and in following years was recognised as occurring in other species of animals; whereas a new variant of Creutzfeldt-Jakob Disease (nv-CJD) was described in 1996; whereas evidence is accumulating that the agent causing BSE is identical to that causing nv-CJD;

(2) Whereas 66 cases of BSE have been notified in Portugal between 1 January 1998 and 14 October 1998; whereas this leads to a BSE incidence rate calculated over the past 12 months of 105,6 cases per million animals over two years of age; whereas two cases have been identified in animals born after implementation of the prohibition on feeding mammalian derived protein to ruminants; whereas the development of the incidence of the disease indicates potential recycling and accumulation of the BSE agent in the Portuguese cattle population;

(3) Whereas missions on BSE-related issues have been carried out in Portugal by the Commission Office for Veterinary and Phytosanitary Inspection and Control from 7 to 12 July 1996 and by the Food and Veterinary Office of the Commission from 15 to 21 June 1997 and from 11 to 15 May 1998; whereas those missions contributed to the assessment of the application and effectiveness of measures to protect against BSE; whereas those missions concluded that, despite important improvements, not all risk factors were adequately managed; whereas a follow-up mission was conducted by the food and Veterinary Office from 28 September to 2 October 1998; whereas that mission confirmed most of the findings of the previous missions and observed, despite an overall improvement, certain continued shortcomings in the enforcement of the measures to control the risk factors; whereas the sharp increase in the incidence of BSE, in particular since June 1998, raises serious concerns with regard to the development of the disease in the near future; whereas on the basis of that mission it is concluded that due to deficiencies existing until very recently in the implementation of Community legislation on identification and registration of animals, and of measures on TSE surveillance and BSE eradication, no adequate guarantees can be provided regarding the BSE history of the herds of origin and herds through which bovine animals pass and regarding the dams of bovine animals;

(4) Whereas the Scientific Steering Committee (SSC) adopted an opinion on BSE risk on 27 March 1998; whereas in that opinion the SSC recognised three major issues in considering the risk of BSE: first, the risk of human exposure arising from the direct consumption of potentially infective material, secondly, the risk to man from ingesting or being exposed to processed, potentially infective material,

[1] OJ L 224, 18. 8. 1990, p. 29.
[2] OJ L 62, 15. 3. 1993, p. 49.
[3] OJ L 395, 30. 12. 1989, p. 13.

and, thirdly, the risk of propagating the infection by recycling the infective material through animal feed; whereas the Code Commission of the International Office of Epizootics (OIE) also proposes that the assessment of the risk to human and animal health in countries, or regions within countries, be based on a combination of the spread of BSE and the application of measures to control the risk;

(5) Whereas, in those circumstances and as an emergency measure, it is appropriate to prohibit temporarily the dispatch from Portugal to the other Member States of all bovine animals and of all products obtained from, or incorporating materials derived from, bovine animals which are liable to enter the human food or animal feed chains or are destined for use in cosmetic or medicinal products or medical devices; whereas in order to prevent deflections of trade, the same prohibitions should also apply to exports to third countries; whereas it is necessary to prohibit temporarily the dispatch from Portugal of mammalian meat-and-bone meal and animal feed and fertilisers containing mammalian meat-and-bone meal, which by their nature could enter the animal feed chain;

(6) Whereas the level of risk of propagating or introducing the disease from live cattle to unaffected animal populations is considered to be considerable; whereas additional measures proposed by Portugal to address the risk of exposing humans and animals to infected material are considered to be adequate; whereas account should be taken of the effective implementation and assessment of effective enforcement of those measures; whereas, therefore, the prohibition on the dispatch of bovine products can be limited in time, provided that a risk assessment conducted on the basis of the findings of a mission of the Food and Veterinary Office, taking into account the evolution of the disease, demonstrates that appropriate measures have been taken to manage any risk, and that the relevant Community and national measures are complied with and effectively enforced; whereas the period foreseen for the prohibition on the export of meat and certain other products could be reduced in the event of a favourable outcome of such risk assessment;

(7) Whereas Council Regulation (EC) No 820/97 of 21 April 1997 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products [1] provides for a system enabling animals to be traced back to the dam and herd of origin; whereas such a system is a prerequisite for effective eradication of BSE and it is necessary for Portugal to ensure that those Community provisions are effectively complied with;

(8) Whereas Commission Decision 98/272/EC of 23 April 1998 on epidemio-surveillance for transmissible spongiform encephalopathies and amending Decision 94/474/EC [2] provides for an on-going education programme to encourage reporting of TSEs, the compulsory notification, movement restriction, possible killing, examination and destruction of suspect animals, the conducting of a sampling and monitoring programme and the annual reporting to the Commission and the Member States of the results of this programme and in particular of the information concerning the number and outcome of clinical and epidemiological investigations of suspect animals; whereas it is justified, in view of the seriousness of the situation, to require Portugal to increase the frequency of reporting to the Commission and the Member States to once every four weeks;

(9) Whereas Commission Decision 96/381/EC of 20 June 1996 approving the measures to be implemented as regards bovine spongiform encephalopathy in Portugal [3] refers to the principle, laid down in point 6 of the conclusions of the Council meeting of 1 to 3 April 1996, that a programme to control BSE and reduce the number of future cases should concentrate on removal of animals, or as appropriate herds, most likely to have been exposed to infected meat-and-bone meal; whereas the main principles of the plan are:

(a) compulsory slaughter of animals identified as imported from the United Kingdom, all animals in herds where cases of BSE have occurred and all animals in other herds identified as belonging to the same birth cohort as affected animals;

(b) and improved system of health monitoring of holdings with bovine animals and intensified surveillance of the feed manufacturing industry to prevent the possible use of meat-and-bone meal;

[1] OJ L 117, 7. 5. 1997, p. 1.
[2] OJ L 122, 24. 4. 1998, p. 59.
[3] OJ L 149, 22. 6. 1996, p. 25.

whereas the Commission accepted under circumstances particular to Portugal and to restore consumer confidence that a whole herd slaughter policy be adopted in Portugal; whereas the plan approved by Decision 96/381/EC provides for the slaughter of all animals belonging to the same birth cohort as affected animals; whereas, therefore, Portugal must identify all animals belonging to the same birth cohort regardless of whether the affected animals were born or reared in the same herd as that to which they belonged at the moment of confirmation of BSE or in another herd;

(10) Whereas the provisions of Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community [1], as last amended by Commission Decision 98/12/EC [2], require each Member State to notify directly to the Commission, at least on the first working day of each week, the secondary outbreaks of BSE confirmed in its territory;

(11) Whereas, in order to protect animal and human health in the Community, the Commission adopted Decision 94/381/EC of 27 June 1994 concerning certain protection measures with regard to bovine spongiform encephalopathy and the feeding of mammalian derived protein [3], as amended by Decision 95/60/EC [4], which prohibited the feeding of mammalian protein to ruminants throughout the Community, Decision 96/449/EC of 18 July 1996 on the approval of alternative heat treatment systems for processing animal waste with a view to the inactivation of spongiform encephalopathy agents [5], which lays down the best available method for processing animal waste as regards spongiform encephalopathy agents, and Decision 97/735/EC of 21 October 1997 concerning certain protection measures with regard to trade in certain types of mammalian animal waste [6];

(12) Whereas Portugal has taken measures as notified to the Commission on 12 October 1998, including measures to prohibit the incorporation of meat-and-bone meal in any animal feed and to require the destruction of meat-and-bone meal; whereas subsequently commitments were given to recall and destroy any stocks of meat-and-bone meal, and of animal feed that contains meat-and-bone meal, present in animal waste processing establishments, feedingstuff producing plants, agricultural establishments or any other place; whereas those measures are considered to reduce the risk of propagating the disease through animal feed;

(13) Whereas Portugal has taken measures to destroy certain risk materials as notified to the Commission on 12 October 1998, including the bovine, ovine, and caprine tissues defined as specified risk materials in Commission Decision 97/534/EC of 30 July 1997 on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies [7], as last amended by Council Decision 98/248/EC [8]; whereas those measures are considered to reduce the risk of exposing humans or animals directly or indirectly to the BSE agent present in risk materials;

(14) Whereas, in those circumstances and as an emergency measure, it is appropriate to require Portugal to implement programmes to demonstrate effective compliance with all relevant Community legislation, this Decision and relevant national legislation, and to report in detail to the Commission every four weeks on the outcome of those programmes;

(15) Whereas strict conditions should apply to derogations from the prohibition for certain products and for products derived from bovine animals slaughtered outside Portugal;

(16) Whereas, in view of the epidemiological situation and the movements of live cattle to the autonomous region of the Azores, this Decision should not apply to that region;

(17) Whereas, with a view to giving financial support to the efforts made by Portugal, the Commission will, as soon as possible, propose appropriate measures;

(18) Whereas the Commission should continue to carry out Community inspections in Portugal to verify the application of the measures provided for in this Decision;

(19) Whereas, pending an overall examination of the situation, this Decision should be reviewed in the light of new scientific information;

(20) Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

[1] OJ L 378, 31. 12. 1982, p. 58.
[2] OJ L 4, 8. 1. 1998, p. 63.
[3] OJ L 172, 7. 7. 1994, p. 23.
[4] OJ L 55, 11. 3. 1995, p. 43.
[5] OJ L 184, 24. 7. 1996, p. 43.
[6] OJ L 294, 28. 10. 1997, p. 7.
[7] OJ L 216, 8. 8. 1997, p. 95.
[8] OJ L 102, 2. 4. 1998, p. 26.

HAS ADOPTED THIS DECISION:

CHAPTER I

SCOPE

Article 1

1. Notwithstanding Community provisions adopted to protect against bovine spongiform encephalopathy (BSE), this Decision lays down emergency measures made necessary by the occurrence of BSE in Portugal.

2. The provisions of this Decision shall not apply to the autonomous region of the Azores.

However, Portugal shall ensure that the provisions of Articles 2 to 12 are applied to the dispatch of consignments from the other parts of Portugal to the Azores.

CHAPTER II

LIVE BOVINE ANIMALS, BOVINE EMBRYOS, MEAT-AND-BONE MEAL AND RELATED PRODUCTS

Article 2

Portugal shall ensure that the following are not dispatched from its territory to other Member States or to third countries:

(a) live bovine animals and bovine embryos;

(b) meat meal, bone meal, and meat-and-bone meal of mammalian origin;

(c) animal feed and fertilisers containing material referred to in (b).

Article 3

By way of derogation from Article 2, food destined for domestic carnivores containing material referred to in Article 2(b) may be dispatched to other Member States or to third countries provided that those materials did not originate from Portugal and that the conditions laid down in Articles 8 and 9 are complied with.

CHAPTER III

MATERIALS DERIVED FROM BOVINE ANIMALS SLAUGHTERED IN PORTUGAL

Article 4

Portugal shall ensure that until 1 August 1999 the following are not dispatched from its territory to other Member States or to third countries, when derived from bovine animals slaughtered in Portugal:

(a) meat;

(b) products which are liable to enter the human food or animal feed chains;

(c) materials which are destined for use in cosmetic or medicinal products or medical devices.

Article 5

1. By way of derogation from Article 4, Portugal may authorise the production and the dispatch from its territory to other Member States or to third countries of:

(a) amino acids, peptides and tallow, which have been produced in establishments under official veterinary supervision which have been shown to be operating in accordance with the conditions set out in the Annex;

(b) tallow products and products derived from tallow by saponification, transesterification or hydrolysis, where these are manufactured from tallow produced in accordance with this Article;

(c) samples, dispatched from the national veterinary laboratories in Lisbon and Porto to officially approved institutes, obtained from bovine animals slaughtered in Portugal and which are destined for use for the purpose of laboratory examination or research into BSE and BSE diagnostic tests.

2. Portugal shall ensure that the products referred to in paragraph 1(a) and (b) are labelled or otherwise identified to show the establishment of production and to indicate that they are suitable for use in human food, animal feed, cosmetics, medicinal products or medical devices.

3. Portugal shall ensure that products referred to in paragraph 1(a) which are dispatched to other Member States in accordance with this Article are accompanied by a health certificate issued by an official veterinarian stating that they conform to the conditions laid down in this Decision and attesting to the frequency of official controls carried out.

4. Before an establishment may commence or recommence the dispatch of products pursuant to this Article, Portugal shall forward to the Commission and the other Member States the list of the establishments referred to in paragraph 1(a), identifying for each establishment the purpose for which it has been approved. It shall notify the Commission and the other Member States immediately of any amendments to that list.

Article 6

Portugal shall ensure that gelatin, di-calcium phosphate, collagen, tallow, tallow products and products derived from tallow by saponification, transesterification or hydrolysis which are produced for technical use from raw materials derived from bovine animals slaughtered in Portugal are labelled or otherwise identified to show the establishment of production and their unsuitability for use in human food, animal feed, cosmetics, medicinal products or medical devices.

CHAPTER IV

MATERIALS DERIVED FROM BOVINE ANIMALS NOT SLAUGHTERED IN PORTUGAL

Article 7

Portugal shall ensure that the provisions of Articles 8 to 12 are complied with when the following products derived from bovine animals not slaughtered in Portugal are dispatched from its territory to other Member States or to third countries:

(a) 'fresh meat' as defined by Council Directive 64/433/EEC ([1]);

(b) 'minced meat' and 'meat preparations' as defined by Council Directive 94/65/EC ([2]);

(c) 'meat products' and 'other products of animal origin' as defined by Council Directive 77/99/EEC ([3]);

(d) food which is destined for domestic carnivores;

(e) gelatin and di-calcium phosphate, tallow, tallow products, and products derived from tallow by saponification, transesterification or hydrolysis, amino acids, peptides and collagen which are liable to enter the human food or animal feed chains, or are destined for use in cosmetic or medicinal products or medical devices.

Article 8

1. The products referred to in Article 7 shall come from and, as appropriate, have passed through, establishments in Portugal:

(a) which have been approved by the competent authority;

(b) which are under official veterinary supervision or, in the case of products derived from tallow by saponification, transesterification or hydrolysis, under the supervision of the competent authority;

(c) which have put in place a system of tracing of the raw material which will guarantee the origin of the material throughout the whole production chain;

(d) which have put in place a registration system of amounts of incoming and outgoing materials to allow for cross-checking consignments entering or leaving;

(e) in which the products are unloaded, processed, stored, handled, loaded and transported separately from, or at different times from, products which do not comply with the conditions laid down in this Article and Articles 9, 10 and 11.

2. Portugal shall forward to the Commission and the other Member States the list of establishments which meet the conditions referred to in paragraph 1, identifying for each establishment the purpose for which it has been approved. It shall notify the Commission and the Member States immediately of any amendments to that list.

Article 9

1. Products referred to in Article 7(a) to (d) shall come from and, as appropriate, have passed through establishments in Portugal:

(a) in which all unloading, processing, storage or other handling and loading of products takes place under official supervision;

(b) in which the products are stored in cold stores in chambers which are not used at the same time for storing any bovine products which do not comply with the conditions laid down in this Article and in Articles 8, 10, 11 and 12 and are kept locked under the seal of the competent authority when the latter is not present;

(c) in which the products are marked or labelled with an additional distinct mark which cannot be confused with the Community health mark;

(d) in which the products eligible for dispatch from Portugal under this Article and Articles 8, 10, 11 and 12, but destined for placing on the market in Portugal do not bear the additional mark referred to in point (c). Where such a mark is present, it shall be cancelled or removed from the meat or cancelled from the label at the time that meat or those products leave the establishment.

Portugal shall forward to the Commission and the other Member States the model of the additional mark.

([1]) OJ 121, 29. 7. 1964, p. 2012/64.
([2]) OJ L 368, 31. 12. 1994, p. 10.
([3]) OJ L 26, 31. 1. 1977, p. 85.

2. For the purposes of the health marking and application of additional marks provided for in Community legislation, the competent authority shall keep and maintain under its responsibility:

(a) the instruments intended for meat health marking and application of additional marks, which may be handed over to auxiliaries only at the time of marking and for the length of time required for that purpose;

(b) any labels bearing a health mark or an additional mark. Those labels shall be serially numbered and the requisite quantity may be given to auxiliaries at the time when they are to be used.

3. The products referred to in paragraph 1 shall be transported in means of transport that are sealed by the competent authority.

When those products are dispatched to other Member States, they shall be accompanied by a health certificate issued by an official veterinarian stating that the conditions referred to in this Article and Articles 8, 10, 11 and 12 are met, identifying all establishments where they were obtained, processed, handled or stored and identifying all labels and their serial numbers in the consignment.

Meat shall be accompanied by the health certificate referred to in Annex IV to Directive 64/433/EEC identifying in the 'Identification of meat' section of the certificate all labels and their serial numbers in the consignment.

The following words shall be added to all certificates:

'produced in accordance with Commission Decision 98/653/EC'.

4. Portugal shall inform the competent authority of the place of destination of each consignment by means of the ANIMO system as referred to in Commission Decision 91/398/EEC [1], or by fax.

Article 10

Without prejudice to Article 9(1)(d), where products referred to in Article 7(a) come from and, as appropriate, have passed through establishments in Portugal, the health marks shall not be removed except where that is unavoidable in the cutting process.

Article 11

The products referred to in Article 7(e) which are dispatched to other Member States shall be labelled in order to identify the establishment of production and to indicate that they have been produced in accordance with this Decision and, as appropriate, that they are suitable for use in human food, animal feed, cosmetics, medicinal products or medical devices.

Article 12

1. A Member State which dispatches meat as referred to in Article 7(a) from an establishment or Community approved border inspection post in its territory through the territory of Portugal or to an establishment approved in accordance with Article 8 shall ensure that the meat is accompanied by a veterinary certificate issued by an official veterinarian or the certificate issued by the competent authority of the border inspection post.

The originals of all certificates shall accompany the consignment to the establishment of its destination.

2. The meat as referred to in Article 7(a) shall be transported in an officially sealed vehicle.

The seal may be broken only for official inspection purposes.

3. A Member State which dispatches products referred to in Article 7(e) or any raw materials for use in the production of those products to an establishment approved in accordance with Article 8 shall ensure that they are labelled or otherwise identified to show the establishment and Member State in which they were produced.

CHAPTER V

MONITORING, REPORTS AND INSPECTIONS

Article 13

1. Portugal shall complete the efforts undertaken, and implement a programme to demonstrate effective compliance with all relevant Community legislation on identification and registration of animals, the notification of animal diseases, epidemio-surveillance for transmissible spongiform encephalopathy (TSE) and with all other Community legislation to protect against BSE.

2. Portugal shall adopt a programme to demonstrate effective compliance with:

(a) the provisions of this Decision;

(b) the relevant national measures to protect against BSE, in particular those on the eradication of BSE.

[1] OJ L 221, 9. 8. 1991, p. 30.

3. The programmes referred to in paragraphs 1 and 2 shall include a permanent monitoring of the application of the provisions and where appropriate physical examination by an approved method of the products concerned.

Article 14

Portugal shall send the Commission every four weeks a report on the application of the protective measures taken against TSEs in accordance with Community and national provisions and on the results of the programmes referred to in Article 13.

Article 15

The Commission shall carry out Community inspections on-the-spot in Portugal to:

(a) verify the application of the provisions of this Decision, in particular in relation to the implementation of official controls;

(b) to examine the development of the incidence of the disease, the effective enforcement of the relevant national measures and to conduct a risk assessment demonstrating whether appropriate measures to manage any risk have been taken.

CHAPTER VI

FINAL PROVISIONS

Article 16

1. This Decision shall be reviewed within 18 months after its adoption at the latest, pending an overall examination of the situation, in particular in view of the development of the incidence of the disease and the effective enforcement of the relevant measures, and in the light of new scientific information.

2. At the request of Portugal, this Decision shall be amended to take account of different control systems that provide equivalent guarantees to the measures provided for in Articles 5 to 12.

3. This Decision shall be amended, where appropriate, after consultation of the appropriate scientific committee, in accordance with the procedure laid down in Article 17 of Directive 89/662/EEC.

Article 17

Member States shall adopt the necessary measures to comply with this Decision. They shall immediately inform the Commission thereof.

Article 18

This Decision is addressed to the Member States.

Done at Brussels, 18 November 1998.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

CHAPTER 1

1. The following products may be exported from Portugal in application of the provisions of Article 5:

   (a) amino acids and peptides produced from hides and skins by a process which involves exposure of the material to a pH of 1 to 2, followed by a ph of > 11, followed by heat treatment of 140 °C for 30 minutes at 3 bar;

   (b) tallow and tallow products produced from material from animals fit for human consumption which have been subjected to one of the processes described in Chapter 2;

   (c) products derived from tallow by one of the processes described in Chapter 3.

2. Products referred to in point 1 must be filtered after production.

3. Bovine animals which are showing signs of BSE may not be used as source material for production of the products referred to in point 1.

4. The following tissues may not be used for production of products referred to in point 1: skull, vertebral column, brain, spinal cord, eye, tonsil, thymus, intestine or spleen.

CHAPTER 2

A. Production standards for tallow produced in Portugal from material derived from bovine animals slaughtered in Portugal

1. Tallow may be produced only in systems described in Chapters I to IV, VI and VII of the Annex to Commission Decision 92/562/EEC [1], in which the following minimum conditions are achieved:

CHAPTER I (batch/atmospheric/natural fat) 150 mm particle size maximum

Temperature	> 100 °C	> 110 °C	> 120 °C
Time	125 min.	120 min.	50 min.

CHAPTER II (batch/pressure/natural fat) 50 mm particle size maximum

Temperature	> 100 °C	> 133 °C
Time	25 min.	20 min.
Pressure (absolute)	3 bar	

CHAPTER III (continuous/atmospheric/natural fat) 30 mm particle size maximum

Temperature	> 100 °C	> 110 °C	> 120 °C
Time	95 min.	55 min.	13 min.

CHAPTERS IV and VI (continuous/atmospheric/added fat and continuous/pressure/added fat) 30 mm particle size maximum

Temperature	> 100 °C	> 110 °C	> 120 °C	> 130 °C
Time	16 min.	13 min.	8 min.	3 min.

[1] OJ L 359, 9. 12. 1992, p. 23.

CHAPTER VII (continuous/atmospheric/defatted) 20 mm particle size maximum

Temperature	> 80 °C	> 100 °C
Time	120 min.	60 min.

The above temperature/time requirements may run concurrently.

2. Portugal may authorize plants only if they have been shown by methods laid down in Section B to be operating in accordance with the conditions set out in point 1.

3. Batch systems which achieve the parameters laid down in point 2 for continuous systems operating in accordance with Chapters III, IV, VI or VII may also be authorised.

B. **Procedures for the validation of plants for the processing of animal waste of ruminant origin for the production of tallow in Portugal, using methods described in the Annex to Decision 92/562/EEC**

1. *Temperature — continuous and batch systems*

Temperature monitoring devices must be situated regularly throughout the equipment in order to record temperature at different stages in the process. Records should be kept and calibrations completed at regular intervals.

2. *Pressure (Chapter II only)*

Pressure monitoring devices must be installed in order to record pressure at stages in the process. Records must be kept and calibrations completed at regular intervals.

3. *Particle size — all systems*

CHAPTER 3

Human food, animal feed, medicinal products or medical devices, their starting materials or intermediate products

Tallow derivatives may be used provided that they are produced by an appropriate, validated and strictly certified method such as:

1. transesterification or hydrolysis at not less than 200 °C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production); or,

2. saponification with NaOH 12M (glycerol and soap production):
   — in a batch process: at not less than 95 °C for not less than 3 hours, or
   — in a continuous process: at not less than 140 °C, 2 bars for not less than 8 minutes, or equivalent.

Cosmetic products, starting materials or intermediate products

Tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer:

1. transesterification or hydrolysis at at least 200 °C, 40 bars for 20 minutes (glycerol and fatty acids and esters); or,

2. saponification with NaOH 12M (glycerol and soap):
   — in a batch process: at 95 °C for 3 hours, or
   — in a continuous process: at 140 °C, 2 bars for 8 minutes or equivalent.