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COUNCIL DECISION

of 16 March 1998

concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC

(98/256/EC)

(OJ L 113, 15.4.1998, p. 32)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Decision 98/564/EC of 7 October 1998	L 273	37	9.10.1998
►**M2**	Commission Decision 98/692/EC of 25 November 1998	L 328	28	4.12.1998
►**M3**	Commission Decision 2002/670/EC of 20 August 2002	L 228	22	24.8.2002

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COUNCIL DECISION

of 16 March 1998

concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC

(98/256/EC)

THE COUNCIL OF THE EUROPEAN UNION,

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], 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 [2], and in particular Article 9(4) thereof,

Having regard to the proposal from the Commission,

(1) Whereas new information has been published in the United Kingdom further supporting the hypothesis that exposure to the bovine spongiform encephalopathy (BSE) agent is linked to the new variant of Creutzfeldt Jacob Disease (CJD) in humans; whereas on 16 September 1997 the Spongiform Encephalopathy Advisory Committee (SEAC) of the United Kingdom concluded that recent research provided compelling new evidence that the agent which causes BSE is identical to the agent which causes the new variant of CJD in humans; whereas on 18 September 1997 the Advisory Committee on Dangerous Pathogens (ACDP) concluded that the BSE agent should now be classified as a human pathogen;

(2) Whereas, in those circumstances and as an emergency measure, it is appropriate to prohibit temporarily the dispatch to the other Member States of all bovine animals from the United Kingdom and of all products consisting entirely or in part of, or incorporating materials derived from, bovine animals slaughtered in the United Kingdom which are liable to enter the human food or animal feed chains or are destined for use in cosmetic, pharmaceutical or medical products; whereas in order to prevent deflections of trade, the same prohibitions should also apply to exports to third countries;

(3) Whereas, in order to protect animal and human health in the Community, the Commission adopted Decision 94/474/EC of 27 July 1994 concerning certain protection measures relating to bovine spongiform encepahalopathy and repealing Decisions 89/469/EEC and 90/200/EEC [3], Decision 92/290/EEC of 14 May 1992 concerning certain protection measures relating to bovine embryos in respect of bovine spongiform encephalopathy (BSE) in the United Kingdom [4], 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 [5] and Decision 96/449/EC of 18 July 1996 on

[1] OJ L 224, 18. 8. 1990, p. 29. Directive as last amended by Directive 92/118/EEC (OJ L 62, 15. 3. 1993, p. 49).
[2] OJ L 395, 30. 12. 1989, p. 13. Directive as last amended by Directive 92/118/EEC.
[3] OJ L 194, 29. 7. 1994, p. 96. Decision as last amended by Decision 95/287/EC (OJ L 181, 1. 8. 1995, p.40).
[4] OJ L 152, 4. 6. 1992, p. 37. Decision as amended by the 1994 Act of Accession.
[5] OJ L 172, 7. 7. 1994, p. 23. Decision as amended by Decision 95/60/EC (OJ L 55, 11. 3. 1995, p. 43).

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the approval of alternative heat-treatment systems for processing animal waste with a view to the inactivation of spongiform encephalopathy agents [1];

(4) Whereas the United Kingdom has taken measures as a result of the publication of information on certain cases of CJD in that Member State;

(5) Whereas the United Kingdom has banned the use of mammalian meat-and-bone meal, regardless of its origin, for feeding farm animals; whereas it is necessary to provide that mammalian meat-and-bone meal and farm animal feed and fertilisers containing mammalian meat-and-bone meal, which by their nature could enter the farm animal feed chain, may not be dispatched from the United Kingdom;

(6) Whereas the risk of transmissible spongiform encephalopathies (TSEs) entering the human food or animal feed chains through the consumption of protein derived from domestic carnivores is considered low; whereas that risk can be further reduced by requiring that domestic carnivores are not fed mammalian meat-and-bone meal originating in the United Kingdom; whereas it is therefore appropriate to provide that food for domestic carnivores which is produced in the United Kingdom but contains no mammalian meat-and-bone meal originating in that country may be dispatched from its territory to other Member States or to third countries;

(7) Whereas the United Kingdom has taken measures to destroy certain bovine tissues;

(8) Whereas Commission Decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy [2], before its amendment by Decision 96/362/EC [3], prohibited the dispatch from the United Kingdom to other Member States and to third countries, in particular, of bovine semen, and certain other products from the United Kingdom obtained from bovine animals slaughtered in the United Kingdom which are liable to enter the animal feed or human food chains and materials destined for use in medicinal products, cosmetics or pharmaceutical products;

(9) Whereas the Scientific Veterinary was consulted on 18 and 26 April 1996; whereas, in the opinion of that Committee, bovine semen is considered to be safe for animal health with respect to BSE;

(10) Whereas the Scientific Committee on Cosmetology was consulted on the safety of certain bovine products on 11 April 1996; whereas the Liaison Committee of European Associations of the Perfume, Cosmetic Products and Toiletries Industries (Colipa) has recommended its members not to use source materials from United Kingdom bovine animals; whereas that Committee has declared that its members follow that recommendation; whereas Commission Directive 97/1/EC of 10 January 1997 adapting to technical progress Annexes II, III, VI, and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products [4], has provisionally prohibited the placing on the market of cosmetic products containing certain tissues and fluids;

(11) Whereas the Scientific Committee for food was consulted on the safety of certain bovine products on 15 April 1996;

(12) Whereas the Committee for Proprietary Medicinal Products was consulted on 16 April 1996; whereas the pharmaceutical sector had already introduced measures relating to the sourcing of

(1) OJ L 184, 24. 7. 1996, p. 43.
(2) OJ L 78, 28. 3. 1996, p. 47.
(3) OJ L 139, 12. 6. 1996, p. 17.
(4) OJ L 16, 18. 1. 1997, p. 85.

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materials and their treatment; whereas every medicinal product undergoes a pre-marketing approval before it is placed on the market by virtue of which the treatment process of any raw material is evaluated; whereas at the request of the European Agency for the Evaluation of Medicinal Products, all Community marketing authorisation holders, or applicants with a positive opinion from the Committee for Proprietary Medicinal Products or the Committee for Veterinary Medicinal Products, have confirmed that the products concerned do not contain bovine tissue of United Kingdom origin;

(13) Whereas subsequently, additional information was made available in order to facilitate a more complete risk assessment; whereas, on that basis, the Scientific Veterinary Committee on 26 April 1996 concluded that a combination of appropriate sourcing of bovine materials used and the application of minimum processing standards whch have been shown effectively to inactivate the BSE agent together give good reassurances about the safety of those materials for food or cosmetic use; whereas, consequently, the Scientific Veterinary Committee has recommended safety parameters for the production of those materials which are therefore considered to be safe;

(14) Whereas the Commission accordingly considered that certain products, such as gelatin and tallow, were safe;

(15) Whereas in 1988 the United Kingdom introduced a requirement for animals affected with BSE to be completely destroyed; whereas the Council, at its meeting on 1, 2 and 3 April 1996, concluded that bovine animals over the age of 30 months should not enter the human food or animal feed chains or be used for cosmetic or pharmaceutical products; whereas such animals should not be used as source materials for certain bovine products;

(16) Whereas furthermore, certain bovine tissues should not be used as source materials for those products;

(17) Whereas Decision 96/362/EC amended Decision 96/239/EC to exempt certain products, such as gelatin, tallow and bovine semen, from the prohibition;

(18) Whereas the Scientific Veterinary Committee at its meeting on 17 July 1996 endorsed the report of the sub-group for BSE of 26 June 1996, where it recommended that the risk assessment for gelatin established by the Scientific Veterinary Committee on 26 April 1996 be reappraised in the light of the uncertainties as to the inactivation of the BSE agent, due note being taken of the requirements of Decision 96/362/EC;

(19) Whereas Decision 96/362/EC laid down certain preconditions which had to be met before the United Kingdom could dispatch from its territory gelatin made from raw materials from bovine animals; whereas those preconditions have not beeen fulfilled and such dispatch has not been authorised; whereas, however, in order to regualarise the situation, pending further scientific knowledge and advice, it is appropriate to withdraw the possibility of dispatch of gelatin made from raw materials from bovine animals slaughtered in the United Kingdom for human food, animal feed, cosmetics pharmaceutical and medical purposes; whereas that is in conformity with the advice from the Multidisciplinary Scientific Committee of 3 April 1997, according to which no production can be considered safe if the base material used for gelatin production is potentially infectious;

(20) Whereas the United Kingdom should be permitted to dispatch rom its territory gelatin and di-calcium phosphate for technical purposes made from raw material from bovine animals slaughtered in the United Kingdom, provided that it is suitably labelled;

(21) Whereas the United Kingdom should also be permitted to disptach from its territory gelatin produced from raw material

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from bovine animals not slaughtered in the United Kingdom; whereas the United Kingdom has introduced a system of traceability for such gelatine to ensure that the origin of the raw material is identifiable; whereas the Community rules should be supplemented by formally introducing a system of traceability; whereas such a system should be introduced for other products which are exempted from the overall ban; whereas a system of labelling should also be introduced;

(22) Whereas it is necessary to provide that products from bovine animals not slaughtered in the United Kingdom should come from approved establishments under official veterinary control which have a system in place to ensure traceability to the origin of the raw materials; whereas, however, dispatch of those products from the United Kingdom may take place inmediately, without prior inspection by the Commission;

(23) Whereas it is necessary to lay down appropriate guarantees for the dispatch from the United Kingdom of certain products obtained from bovine animals which were not slaughtered in the United Kingdom;

(24) Whereas a reliable system of controls throughout the Community is a precondition for the smooth functioning of the beef market; whereas it is clear from the investigations by the Unit on Coordination of Fraud Prevention (UCLAF) and the Food and Veterinary Office of the Commission that there are deficiencies in official controls on production of beef in the United Kingdom for dispatch to other Member States and third countries; whereas it is, therefore, necessary to reinforce the system of veterinary checks in order to prevent fraud;

(25) Whereas reinforced checks should apply to all commercial consignments of fresh meat of bovine animals moving into, through or from the territory of the United Kingdom; whereas it is appropriate to require that all such consignments be sealed and unsealed by the competent authority and accompanied by veterinary certificates and, in the case of intra-Community trade, to require an official notification of the dispatch of a consignment by means of the ANIMO system as referred to in Commission Decision 91/398/EEC of 19 July 1991 on a computerised network linking veterinary authorities (ANIMO) [1], or by fax;

(26) Whereas the veterinary supervision of the processing of meat derived from bovine animals slaughtered elsewhere than in the United Kingdom should also be reinforced;

(27) Whereas the United Kingdom put forward a first proposal for an export certified herds scheme to the Commission on 25 February 1997; whereas the Scientific Veterinary Committee concluded at its meeting of 11 June 1997 that that proposal was not adequate; whereas the United Kingdom put forward a modified proposal dated 1 July 1997; whereas the Scientific Veterinary Committee issued an opinion on that revised proposal on 17 September 1997 stating that the major obstacle to approving the scheme for the entire territory of the United Kingdom was the lack of a comprehensive computerised movement and tracing system and associated database for live cattle in Great Britain but that an adequate system did apear to exist in Northern Ireland; whereas the Committee concluded furthermore that small modifications could be made to minor aspects of the scheme at the request of the competent Commission departments in order to comply with certification or control requirements; whereas the Food and Veterinary Office conducted a feasibility inspection in Northern Ireland from 3 to 7 November 1997; whereas the United Kingdom has agreed to further improvements in line with the recommendations made following that inspection; whereas, therefore, a partial lifting of the prohibition on the dispatch of

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

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products from bovine animals slaughtered in Northern Ireland is appropriate;

(28) Whereas inspections carried out by the Commission services have shown that the system of veterinary checks in Northern Ireland is more effective; whereas, therefore, a step-by-step approach is appropriate, starting with the lifting of the prohibitions on the dispatch of products from bovine animals slaughtered, cut, processed and stored in establishments exclusively used for products destined for dispatch to other Member States and third countries, located in Northern Ireland; whereas subsequent steps will include the lifting of the prohibition on the processing of eligible meat from Northern Ireland in Great Britain, under conditions which will be laid down at a later stage: whereas the Commission will immediately start investigating, with the authorities of the United Kingdom, by what means and under what conditions those restrictions may be further relaxed;

(29) Whereas in order to prevent fraud, meat derived from bovine animals slaughtered in the United Kingdom should bear, in addition to the health mark provided for in Article 3(1)(A)(e) of Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat [1], a distinct mark which cannot be confused with the Community health mark;

(30) Whereas most of the provisions of Decision 94/474/EC are no longer in conformity with the opinion of the Scientific Veterinary Committee of 17 September 1997 and should therefore be deleted;

(31) Whereas Decision 96/239/EC required the United Kingdom to provide reports on the BSE situation every two weeks; whereas that period has been found to be too short; whereas it should be extended to one month;

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

(33) Whereas the foregoing entails a fundamental reworking of Decision 96/239/EC; whereas, in the interests of clarity, that Decision should be repealed;

(34) Whereas this Decision will be reviewed in the light of new scientific information;

(35) Whereas the Standing Veterinary Committee has not given a favourable opinion,

HAS ADOPTED THIS DECISION:

CHAPTER I

Live bovine animals, bovine embryos, meat-and-bone meal and related products

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Article 1

Pending an overall examination of the situation, and notwithstanding Community provisions adopted to protect against BSE, the United Kingdom shall ensure that the following are not dispatched from its territory to other Member States or to third countries:

(a) live bovine animals;

[1] OJ 121, 29. 7. 1964, p. 2012/64. Directive as last amended by Directive 95/23/EC (OJ L 243, 11. 10. 1995, p. 7).

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

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

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Article 2

By way of derogation from Article 1, food destined for domestic carnivores containing material referred to in Article 1(b) may be dispatched to other Member States or to third countries provided that those materials did not originate from the United Kingdom and that the conditions laid down in Articles 9 and 10 are complied with.

CHAPTER II

Materials derived from bovine animals slaughtered in the United Kingdom

Article 3

Pending an overall examination of the situation, and notwithstanding Community provisions adopted to protect against BSE, the United Kingdom shall ensure that the following are not dispatched from its territory to other Member States or to third countries, when derived from bovine animals slaughtered in the United Kingdom:

(a) meat;

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

(c) materials which are destined for use in cosmetics or medical or pharmaceutical products.

Article 4

1. By way of derogation from Article 3, the United Kingdom 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 Annex I;

(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;

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(c) samples, dispatched from the Veterinary Laboratory Agency, Weybridge, to officially approved institutes, obtained from bovine animals slaughtered in the United Kingdom and which are destined for use for the purpose of research into BSE and BSE diagnostic tests.

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2. The United Kingdom shall ensure that the products referred to in paragraph 1 ►M1 (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 or medical or pharmaceutical products.

3. The United Kingdom 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, the United Kingdom shall forward to the Commission and the other Member States the list of the

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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.

5. Community inspections shall be carried out on the implementation of official controls in respect of each of the products referred to in paragraph 1 before the dispatch of those products may commence or recommence.

6. The Commission, after having consulted the Member States in the framework of the Standing Veterinary Committee, shall set the date on which establishments may commence or recommence dispatch of the products referred to in paragraph 1(a).

Article 5

The United Kingdom 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 the United Kingdom are labelled or otherwise identified to show the establishment of production and their unsuitability for use in human food, animal feed, cosmetics or medical or pharmaceutical products.

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Article 6

1. By way of derogation from Article 3, the United Kingdom may authorise the dispatch to other Member States or third countries of the following products derived from bovine animals born and reared in the United Kingdom which have been slaughtered in the United Kingdom in accordance with the conditions laid down in Article 7, Articles 9 to 12 and Annex II, or as appropriate, Annex III:

(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' as defined by Council Directive 77/99/EEC [3];

(d) food which is destined for domestic carnivores.

2. The fresh meat referred to in paragraph 1(a), if obtained from animals more than nine months old, shall be deboned and all adherent tissues including obvious nervous and lymphatic tissues shall be removed.

3. Cutting, storage and transport of the fresh meat referred to in paragraph 1(a) shall be carried out in accordance with the conditions laid down in Article 7, Articles 9 to 12 and Annex II or, as appropriate, Annex III. The fresh meat may be used for the production of products referred to in (b), (c) and (d) in accordance with the conditions laid down in this article, in Article 7, Articles 9 to 12 and Annex II or, as appropriate, Annex III.

4. The bovine animals referred to in paragraph 1 shall be slaughtered at different times from cattle which do not meet the requirements of Annex II, or as appropriate, Annex III. There shall be a secure sorting and separation of live animals prior to slaughter to ensure that only eligible animals enter the slaughter line during time periods dedicated to such slaughter. Before the commencement of a period of slaughter of eligible animals, the slaughter hall must first be cleansed and disinfected.

5. The dispatch of products referred to in Annex III may commence 1 August 1999.

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[1] OJ L 195, 28.7.1999, p. 42.
[2] OJ 121, 29.7.1964, p. 2012/64.
[3] OJ L 368, 31.12.1994, p. 10.

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Article 7

1. The meat and products referred to in Article 6(1) shall be marked or labelled with an additional distinct mark which cannot be confused with the Community health mark.

2. Meat and products as referred to in Article 6(1) which are destined for placing on the market in the United Kingdom shall not bear the additional mark referred to in paragraph 1 of this Article. 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. The Community health mark shall not be removed except where that is unavoidable in the cutting process.

3. The United Kingdom shall forward to the Commission and the other Member States the model of the additional mark referred to in paragraph 1 before dispatch commences.

CHAPTER III

Materials derived from bovine animals not slaughtered in the United Kingdom

Article 8

The United Kingdom shall ensure that the provisions of Articles 9 to 13 are complied with when the following products derived from bovine animals not slaughtered in the United Kingdom are dispatched from its territory to other Member States or to third countries:

(a) 'fresh meat' as defined by Directive 64/433/EEC;

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

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

(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 cosmetics or medical or pharmaceutical products.

Article 9

1. The products referred to in Article 8 shall come from and, as appropriate, have passed through, establishments in the United Kingdom:

(a) which have been approved by the comptetent 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 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 10, 11 and 12.

2. The United Kingdom 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.

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Article 10

1. Products referred to in Article 8(a) to (d) shall come from and, as appropriate, have passed through establishments in the United Kingdom in which:

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

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(b) (i) non-packaged 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, in Articles 6, 9, 11, 12 and 13 and are kept under the seal of the competent authority when the latter is not present;

(ii) packaged products are stored in cold stores so as to provide a clear and effective segregation from bovine products which do not comply with the conditions laid down in this Article and in Articles 6, 9, 11, 12 and 13;

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(c) the products, with the exception of the products referred to in Article 8(d), are marked or labelled with an additional distinct mark which cannot be confused with the Community health mark;

(d) the products eligible for dispatch from the United Kingdom within the meaning of this Article and Articles 9, 11, 12 and 13, but destined for placing on the market in the United Kingdom 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.

The United Kingdom shall forward to the Commission and the other Member States the model of the additional mark.

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 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 by 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 9, 11, 12 and 13 are met, identifying all establishments where they were obtained, processed, handled or stored and identifying all labels and ►**M2** the relevant numbers in the consignment ensuring traceability of each individual unit ◄.

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 ►**M2** the relevant numbers in the consignment ensuring traceability of each individual unit ◄.

The following words shall be added to all certificates:

'produced in accordance with Decision 98/256/EC'.

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Where those products are dispatched to third countries, they shall be accompanied by a health certificate, issued by an official veterinarian,

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stating that the conditions laid down in Decision 98/256/EC have been complied with.

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4. The United Kingdom shall inform the competent authority of the place of destination of each consignment by means of the Animo system or by fax.

Article 11

Without prejudice to Article 7(2) and Article 10(1)(d), where products referred to in Article 8(a) come from and, as appropriate, have passed through establishments in the United Kingdom, the Community health marks shall not be removed except where that is unavoidable in the cutting process.

Article 12

The products referred to in Article 8(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 or medical or pharmaceutical products.

Article 13

1. A Member State which dispatches meat as referred to in Article 8(a) from an establishment or Community approved border inspection post in its territory through the territory of the United Kingdom or to an establishment approved in accordance with Article 9 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 8(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 8(e) or any raw materials for use in the production of those products to an establishment approved in accordance with Article 9 shall ensure that they are labelled or otherwise identified to show the establishment and Member State in which they were produced.

CHAPTER IV

Final provisions

Article 14

The Commission shall carry out Community inspections on-the-spot in the United Kingdom to verify the application of the provisions of this Decision, in particular in relation to the implementation of official controls.

Article 15

The United Kingdom shall send the Commission every month a report on the application of the protective measures taken against BSE, in accordance with national and Community provisions.

Article 16

This Decision shall be reviewed regularly in the light of new scientific information. This Decision shall be amended, where appropriate, after consultation of the appropriate Scientific Committee, in accordance with the procedure laid down in Article 18 of Directive 89/662/EEC.

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Article 17

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

Article 18

Decision 94/474/EC is hereby amended as follows:

1. Article 1 shall be deleted;
2. in Article 3, paragraphs 1 and 2 shall be deleted;
3. Article 4 shall be deleted.

Article 19

Decision 96/239/EC is hereby repealed.

Article 20

This Decision is addressed to the Member States.

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ANNEX I

CHAPTER 1

1. The following products may be exported from the United Kingdom by virtue of Articles 4 to 7:

   (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 at 140 ºC for 30 minutes at 3 bar,

   (b) tallow and tallow products produced from material from animals fit for human consumption which has 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 and animals over 30 months of age may not be used as source materials (as provided for by Commission Regulation (EC) No 716/96) [1] 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 the United Kingdom from material derived from bovine animals slaughtered in the United Kingdom**

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 [2], in which the following minimum conditions are achieved:

CHAPTER I	(Batch/atmospheric/natural fat) 150 mm particle size maximum			
	Temperature	> 100 ºC	>110ºC	> 120 ºC
	Time	125 min	120min	50 min
CHAPTER II	(Batch/pressure/natural fat) 50 mm particle size maximum			
	Temperature	> 100 ºC	>133ºC	
	Time	25 min	20 min	
	Pressure (absolute) 3 bar			
CHAPTER III	(Continuous/atmospheric/natural fat) 30 mm particle size maximum			
	Temperature	> 100 ºC	>110ºC	> 120 ºC
	Time	95 min	55 min	13 min
CHAPTER IV and VI	(Continuous/atmospheric/added fat and continuous/pressure/added fat) 30 mm particle size maximum			
	Temperature	> 100 ºC	>110ºC	> 120 ºC >130ºC
	Time	16 min	13 min	8 min 3 min
CHAPTER VII	(Continuous/atmospheric/defatted) 20 mm particle size maximum			
	Temperature	> 80 ºC	>100ºC	
	Time	120 min	60 min	

The above temperature/time requirements may run concurrently.

[1] OJ L 99, 20. 4. 1996, p. 14.
[2] OJ L 359, 9. 12. 1992, p. 23.

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2. The United Kingdom may authorise 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 the United Kingdom, 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, medical or pharmaceutical products, 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 ºC 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 ºC for not less than three hours; or,
   — in a continuous process: at not less than 140 ºC, 2 bars for not less than eight 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 ºC, 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 ºC for three hours; or,
   — in a continuous process: at 140 ºC, 2 bars for eight minutes or equivalent.

▼M2

ANNEX II

EXPORT CERTIFIED HERDS SCHEME (ECHS)

▼M3

1. Fresh meat, and products referred to in Article 6(1)(b), (c) and (d) from that meat, derived from bovine animals slaughtered in Northern Ireland, may be dispatched from the United Kingdom in application of the provisions of Article 6 when obtained from ECHS-eligible animals which originate from ECHS-eligible herds. If obtained from animals more than nine months old, the fresh meat shall be deboned and all adherent tissues including obvious nervous and lymphatic tissues shall be removed.

▼M2

ECHS-eligible herds

2. A herd is a group of animals forming a separate and distinct unit, that is a group of animals which were managed, housed and kept separately from any other group of animals and which were identified with unique herd and animal identification numbers.

3. A herd is ECHS-eligible when for at least eight years, there has been no confirmed case of BSE, nor a suspect case for which the diagnosis of BSE has not been ruled out, in any animal which was still in or had moved through or from the herd.

4. A herd that has been in existence for less than eight years may be considered ECHS-eligible, after a thorough epidemiological investigation by the competent veterinary authority, on condition that:

   (a) all animals born or moved into the newly established herd complied with the conditions set out in point 6(a), (c), (d) and (e); and,

   (b) the herd has complied with the conditions set out in point 3 during its entire existence.

5. If a herd is newly established on a holding which experienced a confirmed case of BSE in any animal which was still in or had moved through or from a herd on that holding, the newly established herd can only be ECHS-eligible after a thorough epidemiological investigation by the competent veterinary authority, taking into account compliance with each of the following conditions to the satisfaction of the competent veterinary authority:

   (a) all animals of the affected herd previously established on the same holding have been removed or killed;

   (b) all feed has been removed and destroyed and all feed containers thoroughly cleansed;

   (c) all buildings have been emptied and thoroughly cleansed before the new animals were admitted;

   (d) all conditions set out in point 4 have been complied with.

ECHS-eligible animals

6. A bovine animal is ECHS-eligible if it has been born and reared in Northern Ireland and at the time of slaughter:

   (a) the animal has been clearly identifiable throughout its life, enabling it to be traced back to the herd and dam of origin; all records of its birth, identity and movements are recorded on an official computerised tracing system;

   (b) it is more than six months but less than 30 months of age, determined by reference to an official computer record of its date of birth;

   (c) its dam has lived for at least six months after its birth;

   (d) its dam has not developed BSE and is not suspected of having contracted BSE;

   (e) the herd of birth of the animal and all herds through which it has ever moved are ECHS-eligible.

7. The official computerised tracing system referred to in point 6(a) will be accepted only where it has been in operation for sufficient time to contain all the information relating to the lifetime and movements of the animals needed to check compliance with the requirements of this Decision, and only in respect of animals born after the system came into operation. Historical data loaded into a computer for any period before the system was operational will not be accepted for this purpose.

▼M2

Controls

8. If any animal presented for slaughter or any circumstance surrounding its slaughter does not meet all of the requirements of this Decision, the animal must be automatically rejected. If that information becomes available after slaughter, the competent authority must immediately cease issuing certificates, and cancel issued certificates. If dispatch has already taken place, the competent authority must notify the competent authority of the place of destination. The competent authority of the place of destination must take the appropriate measures.

▼M3

9. Slaughter of ECHS-eligible animals must take place in slaughterhouses which operate a system of time separation as set out in Article 6(4).

▼M2

10. The competent authority must ensure that procedures used in the cutting plants ensure that the following lymph nodes have been removed:

    popliteal, ischiatic, superficial inguinal, deep inguinal, medial and lateral iliac, renal prefemoral, lumbar, costocervical, sternal, prescapular, axilliary and caudal deep cervical.

11. Meat must be traceable back to the herd of the ECHS-eligible animal, or after cutting, to the animals cut in the same batch, by means of the computerised tracing system until the time of slaughter. After slaughter, labels must be capable of tracing fresh meat and products referred to in Article 6(1)(b) and (c) back to the herd to enable the consignment concerned to be recalled. Food for domestic carnivores must be traceable by means of accompanying documents and records.

12. All approved ECHS-eligible carcasses must have individual numbers correlated with the ear tag number.

13. The United Kingdom must have detailed protocols in place covering:

    (a) tracing and controls prior to slaughter;

    (b) controls during slaughter;

    (c) controls during processing of food for domestic carnivores;

    (d) all labelling and certification requirements after slaughter to the point of sale.

14. The competent authority must set up a system for recording checks on compliance so that control can be demonstrated.

The establishment

15. To obtain approval, the establishment must, in addition to all other requirements of this Decision, devise and implement a system whereby the ECHS-eligible meat and/or ECHS-eligible product is identifiable and all meat can be traced back to its herds of origin, or after cutting, to the animals cut in the same batch. The system must facilitate full traceability of the meat or products at all stages and records must be retained for at least two years. Details of the system to be employed must be given, in writing, by the management of the establishment to the competent authority.

16. The competent authority must assess, approve and monitor the system provided by the establishment in order to ensure that it provides full segregation and traceability both backwards and forwards.

▼M2

ANNEX III

DATE-BASED EXPORT SCHEME (DBES)

▼M3

1. Fresh meat, and products referred to in Article 6(1)(b), (c) and (d) from that meat, derived from bovine animals slaughtered in the United Kingdom, may be dispatched from the United Kingdom in application of the provisions of Article 6 when obtained from DBES-eligible animals born after 1 August 1996. If obtained from animals more than nine months old, the fresh meat shall be deboned and all adherent tissues including obvious nervous and lymphatic tissues shall be removed.

▼M2

2. Before dispatch pursuant to point 1 may commence, the United Kingdom must have implemented and effectively enforced a programme for the killing and incineration of all offspring born after 1 August 1996 of dams in which BSE has been confirmed before 25 November 1998, and must have killed and incinerated all cattle found alive which were identified under this programme.

   Should confirmation take place after 25 November 1998, offspring born after 1 August 1996 of dams in which BSE has been confirmed, must be identified, slaughtered and incinerated without delay.

DBES-eligible animals

3. A bovine animal is DBES-eligible if it has been born and reared in the United Kingdom and at the time of slaughter the following conditions are shown to have been met:

   (a) the animal has been clearly identifiable throughout its life, enabling it to be traced back to the dam and herd of origin; its unique eartag number, date and holding of birth and all movements after birth are recorded either in the animal's official passport or on an official computerised identification and tracing system; the identity of its dam is known;

   (b) the animal is more than six months but less than 30 months of age, determined by reference to an official computer record of its date of birth, and in the case of animals from Great Britain, the animal's official passport;

   (c) the competent authority has obtained and verified positive official evidence that the dam of the animal has lived for at least six months after the birth of the eligible animal;

   (d) the dam of the animal has not developed BSE and is not suspected of having contracted BSE.

Controls

4. If any animal presented for slaughter or any circumstance surrounding its slaughter does not meet all of the requirements of this Decision, the animal must be automatically rejected. If that information becomes available after slaughter, the competent authority must immediately cease issuing certificates, and cancel issued certificates. If dispatch has already taken place, the competent authority must notify the competent authority of the place of destination. The competent authority of the place of destination must take the appropriate measures.

▼M3

5. Slaughter of DBES-eligible animals must take place in slaughterhouses which operate a system of time separation as described in Article 6(4). Slaughter in Northern Ireland of DBES-eligible animals originating from Great Britain, or vice versa, is only authorised if access to all relevant data is ensured.

▼M2

6. The competent authority must ensure that procedures used in the cutting plants ensure that the following lymph nodes have been removed:

   popliteal, ischiatic, superficial inguinal, deep inguinal, medial and lateral iliac, renal prefemoral, lumbar, costocervical, sternal, prescapular, axilliary and caudal deep cervical.

7. Meat must be traceable back to the DBES-eligible animal, or after cutting, to the animals cut in the same batch, by means of an official tracing system until the time of slaughter. After slaughter, labels must be capable of tracing fresh meat and products referred to in Article 6(1)(b) and (c) back to the eligible animal to enable the consignment concerned to be recalled. Food

▼M2

for domestic carnivores must be traceable by means of accompanying documents and records.

8. All approved DBES-eligible carcasses must have individual numbers correlated with the ear tag number.

9. The United Kingdom must have detailed protocols in place covering:

   (a) tracing and controls prior to slaughter;

   (b) controls during slaughter;

   (c) controls during processing of food for domestic carnivores;

   (d) all labelling and certification requirements after slaughter to the point of sale.

10. The competent authority must set up a system for recording checks on compliance so that control can be demonstrated.

The establishment

11. To obtain approval, the establishment must, in addition to all other requirements of this Decision, devise and implement a system whereby the DBES-eligible meat and/or DBES-eligible product is identifiable and all meat can be traced back to the DBES-eligible animal, or after cutting, to the animals cut in the same batch. The system must facilitate full traceability of the meat or products at all stages and records must be retained for at least two years. Details of the system to be employed must be given, in writing, by the management of the establishment to the competent authority.

12. The competent authority must assess, approve and monitor the system provided by the establishment in order to ensure that it provides full segregation and traceability both backwards and forwards.