

COUNCIL DIRECTIVE

of 17 December 1992

laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC

92/118/EEC

(OJ L 62, 15.3.93. p.49)

amended by 94/466/EC (OJ L 190, 26.7.94, p. 26)

amended by 94/723/EC (OJ L 288, 9.11.94, p. 48)

amended by Accession Treaty

amended by 95/338/EC (OJ L 200, 24.8.95, p. 35)

amended by 95/339/EC (OJ L 200, 24.8.95, p. 36)

amended by 96/103/EC (OJ L 24, 31.1.96, p. 28)

amended by 96/340/EC (OJ L 129, 30.5.96, p. 35)

amended by 96/405/EC (OJ L 165, 4.7.96, p. 40)

amended by 96/90/EC (OJ L 13 16.01.97 p. 24)

amended by 97/79/EC (OJ L 24 30.1.98 p. 31)

amended by 1999/724/EC (OJ L 290, 12.11.1999, p. 32)

amended by 2001/7/EC (OJ No. L 2, 05.01.2001, p. 27)

amended by 2002/33/EC (OJ No. L 315, 19.11.2002, p. 14)

amended by 2003/42/EC (OJ No. L 13, 18.01.2003, p. 24)

amended by 2003/721/EC (OJ No. L 260, 11.10.2003, p. 21)

amended by (EC) No 445/2004 (OJ No. L 72, 11.03.2004, p. 60)

amended by ACT of 2004

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposals from the Commission,

Having regard to the opinions of the European Parliament,

Having regard to the opinions of the Economic and Social Committee,

Whereas

92/118/EC

Whereas products of animal origin are included in the list of products in Annex II to the Treaty; whereas the placing on the market of such products constitutes an important source of income for part of the farming population;

Whereas in order to ensure rational development in this sector and increase productivity, animal health and public health rules for the products in question should be laid down at Community level;

Whereas the Community must adopt the measures intended progressively to establish the internal market consisting of an area without internal frontiers, over a period expiring on 31 December 1992;

Whereas in view of the abovementioned objectives the Council has laid down animal health rules applicable to fresh meat, poultrymeat, meat products, game meat, rabbit meat and milk products;

Whereas, save where otherwise provided, trade in products of animal origin must be liberalized, without prejudice to recourse to possible safeguard measures;

Whereas, given the significant risk of the spread of diseases to which animals are exposed, for certain products of animal origin particular requirements should be specified to be imposed when they are placed on the market for the purposes of trade, particularly when intended for regions with a high health status;

Whereas, when Directive 92/65/EEC was adopted, the Commission agreed to disassociate the animal health aspects applicable to animals from those applicable to products;

Whereas, so as to allow checks at borders between Member States to be abolished on 1 January 1993, animal health and public health rules should be fixed to apply to all products subject to such checks trade in and imports of which have not yet been harmonized at Community level;

Whereas, to achieve this objective, certain existing rules should be adapted for the adoption of the aforesaid measures;

Whereas a system of approval should be introduced for the third countries and establishments which meet the requirements laid down by this Directive, together with a Community inspection procedure to ensure that the conditions for such approval are observed;

Whereas the accompanying document for products is the best way of satisfying the competent authority of the place of destination that a consignment complies with the provisions of this Directive; whereas the public health or animal health certificate should be maintained for the purposes of verifying the destination of certain imported products;

Whereas the rules, principles and safeguard measures established by Council Directive 90/675/EEC (Note by MediaLex: since 1 July 1999, Council Directive 97/78/EC, of 18.12.1997) of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries (4) should apply here;

Whereas, in the context of intra-Community trade, the rules laid down in Directive 89/662/EEC should also be applied;

Whereas the Commission should be entrusted with the task of adopting certain measures for implementing this Directive; whereas, to that end, procedures should be laid down establishing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas, in view of the particular supply difficulties arising from its geographical situation, special derogations should be permitted for the Hellenic Republic;

Whereas the adoption of specific rules for the products covered by this Directive is without prejudice to the adoption of rules on food hygiene and safety in general, on which the Commission has submitted a proposal for a framework Directive,

HAS ADOPTED THIS DIRECTIVE:

94/466/EC

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/118/EEC of 17 December 1982 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (1), and in particular the second paragraph of Article 15 thereof,

Whereas, given the experience gained during the application of the measures provided for, the conditions under which game trophies are traded and imported should be amended; whereas, therefore, Annex I (13) to the above Directive should be reworded;

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

HAS ADOPTED THIS DECISION:

94/723/EC

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC, as amended by Commission Decision 94/466/EC, and in particular the second paragraph of Article 15 thereof,

Whereas, in the light of experience gained in the application of the provisions laid down, the conditions governing trade in and imports of hides and skins of ungulates not covered by Directive 64/433/EEC or 72/462/EEC should be amended; whereas Chapter 3 of Annex I to that Directive should be redrafted accordingly;

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

HAS ADOPTED THIS DECISION:

95/338/EC

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC, as last amended by Commission Decision 95/339/EC, and in particular the second paragraph of Article 15 thereof,

Whereas application of the rules laid down has led to certain difficulties with the import of meat products obtained from poultrymeat, farmed game meat, wild game meat and rabbit meat; whereas, therefore, those rules should be amended in the light of experience;

Whereas those conditions are intended to provide for the possibility of establishing a list of third countries from which the import of the said products is authorized;

Whereas, for reasons of clarity, Chapter 1 of Annex II to Directive 92/118/EEC should be redrafted;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

95/339/EC

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC, as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular the second paragraph of Article 15 thereof,

Whereas, following the opinion of the Scientific Veterinary Committee, the type of treatments to be applied and the requirements laid down should be extended to all milk products and colostrum;

Whereas for the sake of clarity, Chapter I of Annex I to Directive 92/118/EEC should be redrafted;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,
HAS ADOPTED THIS DECISION:

96/340/EC

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC, as last amended by Commission Decision 96/103/EC, and in particular the second paragraph of Article 15 and Annex II Chapter 2 thereof,

Whereas the specific public health conditions applicable to snails and frogs' legs should be laid down in order to prevent these products presenting a threat to consumer health;

Whereas certain health conditions contained in Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products are relevant for trade in snails and frogs' legs;

Whereas the rules contained in Commission Decision 94/356/EC of 20 May 1994 laying down detailed rules for the application of Council Directive 91/493/EEC as regards own health checks on fishery products (4) are relevant for own health checks carried out by establishments producing snails and frogs' legs as referred to in Article 4, point 2 of Directive 92/118/EEC;

Whereas cooked prepared snails should be regarded as prepared meals and subject to the provisions of Chapter IX of Annex B to Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the production and marketing of meat products and certain other products of animal origin, as last amended by Directive 95/68/EC;

Whereas equivalent conditions should apply to snails and frogs' legs imported from third countries; whereas in particular the specimens of the health certificates provided for in Article 10 (2) (c) of Directive 92/118/EEC should be drawn up;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,
HAS ADOPTED THIS DECISION:

96/90/EC

Having regard to the proposal from the Commission

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC, provides for the drawing up of Community lists of establishments for which the competent authority in the third country has given the Community guarantees that the establishments in question comply with Community requirements;

Whereas for ungulate skins, bones, horns, hooves and products thereof, apiculture products, game trophies, slurry, wool, hair, bristles and feathers listed respectively in Annex I, Chapters 3, 5 (B), 12, 13, 14 and 15, and honey it is sufficient to ensure that the establishment has been registered by the competent authority in the third country;

Whereas, because the meat of reptiles and species not covered by specific requirements and products derived from them are being consumed in the Community, health conditions should be laid down on the production, placing on the market and importation of these animal products;

Whereas 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 applies to milk and product derived from milk produced by cows, ewes, and buffaloes only,

Whereas trade in and imports of milk and milk-based products obtained from other species should be subject to specific health conditions;

Whereas, for that purpose, it is essential to entrust to the Commission, in accordance with the Standing Veterinary Committee procedure, the task of adopting the necessary implementing measures to ensure uniform health conditions for production, placing on the market and importation of these animal products;

Whereas it should be laid down that this Directive shall apply without prejudice to Council Regulation (EEC)No 3626/82 of 3 December 1982 on the implementation in the Community of the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

HAS ADOPTED THIS DIRECTIVE:

1999/274/EC

(1) Whereas specific rules applicable to the preparation of gelatine intended for pharmaceutical, cosmetic or other technical use and medical devices are under preparation; whereas, therefore, the regulation of these products may be excluded from the scope of this Decision;

(2) Whereas the specific public health conditions applicable to the preparation of gelatine intended for human consumption should be laid down; whereas, provided that these conditions are the same for gelatine intended for human consumption and gelatine not intended for human consumption and provided that hygiene conditions are also the same, both types of gelatine may be produced and/or stored in the same establishment;

- (3) *Whereas the authorisation and registration, inspection and hygiene requirements which establishments preparing gelatine must meet should be determined; whereas certain health conditions contained in Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the production and marketing of meat products and certain other products of animal origin, as last amended by Directive 97/176/EC, and in Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs, are relevant for the preparations of gelatine;*
- (4) *Whereas the Scientific Steering Committee adopted an opinion on safety of gelatine on 26 and 27 March 1998 which was updated on 18 and 19 February 1999; whereas this opinion addresses the questions under which conditions of sourcing of the material and or of type of material used and/or production process gelatine destined for human consumption can be considered free of bovine spongiform encephalopathy (BSE) infectivity; whereas in this opinion, the Scientific Steering Committee distinguishes the recommended measures between different categories of geographical risk; whereas a final implementation can only follow after classification of countries and regions; whereas on 21 May 1999, at the general session of the International Office of Epizootics (IOE) Committee, a proposal of the IOE International Animal Health Code Commission concerning the criteria for the determination of the BSE Status of a country or zone was adopted; whereas in accordance to the procedure laid down in Commission Recommendation 98/477/EC, concerning information necessary to support applications for the evaluation of the epidemiological status of countries with respect to transmissible spongiform encephalopathies, certain Member States and third countries submitted data necessary to allow assessment of their geographical risk; whereas, considering recent development of the IOE Code on BSE, pending the above scientific assessment and the subsequent decision making, the entry into force of rules for the production of gelatine derived from ruminant bones should be suspended until Community legislation concerning classification of countries or regions as regards their BSE status is applicable; whereas the Commission will initiate the procedure for the entry into force of rules for the production of gelatine derived from ruminant bones without delay after the adoption of Community legislation concerning classification of countries or regions as regards their BSE status;*
- (5) *Whereas the Commission as adopted Decision 97/534/EC, as last amended by Council Decision 98/745/EC on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies;*
- (6) *Whereas the Commission has adopted Decision 98/272/EC on epidemio-surveillance for transmissible spongiform encephalopathies and amending Decision 94/474/EC; whereas this Decision lays down measures to be applied in case of animals suspected of having a transmissible spongiform encephalopathy (TSE);*
- (7) *Whereas a revision of the Animal Health Code of the (IOE) on BSE (IOE Code on BSE) was adopted in the general assembly of the IOE in Paris on 29 May 1998; whereas Article 3.2.13.3 of that Code recommends that if gelatine and collagen are prepared exclusively from hides and skins derived from healthy animals, veterinary administration can authorise, without restriction, the import and transit through their territories of this gelatine and collagen, regardless the status of the exporting countries; whereas Article 3.2.13.15 of that Code recommends under which sourcing and processing conditions gelatine and collagen prepared from bones can be traded;*
- (8) *Whereas gelatine is prepared from bones, farmed ruminant and wild game hides and skins, pig and poultry skins, tendons and sinews and fish skins and bones; whereas supervised hygienic slaughtering of cattle in a slaughterhouse prevents contamination of hides with material presenting risks as regards transmissible spongiform encephalopathies; whereas it is appropriate that these raw materials originate from healthy animals and are dealt with hygienically when being collected, transported stored and handled; whereas in order to guarantee traceability of these raw materials it is appropriate to require collection centres and tanneries which intend to supply these materials to be authorised and registered, whereas, furthermore, it is appropriate to lay down a model of commercial document which should accompany these raw materials during transportation a time of delivery in the collection centres and in the tanneries and in the gelatine processing plants;*
- (9) *Whereas the Scientific Steering Committee in the above opinion strongly recommends that gelatine manufacturers implement and respect hazard analysis and critical control points procedures; whereas the measures relating to establishments' own checks provided for in Article 7 of Directive 77/99/EEC are relevant for own checks carried out by establishments producing gelatine as referred to in Article 4(2) of Directive 92/118/EEC;*
- (10) *Whereas standards for the finished product should be fixed in order to ensure that it is not contaminated by substances or micro-organisms presenting a threat to the health of consumers; whereas pending a scientific evaluation of such standards, it is appropriate to provisionally include generally accepted standards as regards contamination;*
- (11) *Whereas requirements as regards packaging, storage and transport of the finished product should be laid down;*
- (12) *Whereas it is necessary to lay down specific health rules governing the importation of raw materials destined to the production of gelatine intended for human consumption and of gelatine intended for human consumption; whereas where it is possible to recognise conditions offering equivalent guarantees, a third country may submit a proposal for such recognition to the Commission for appropriate consideration;*
- (13) *Whereas the adoption of specific rules for gelatine production is without prejudice to the adoption of rules for the organisation of the prevention and control of transmissible spongiform encephalopathies;*
- (14) *Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,*
HAS ADOPTED THIS DECISION:

2001/7/EC

- (1) *There are some linguistic translation differences between the German text and the other language versions concerning the cross-border trade in unprocessed manure which should be resolved and it is opportune in view of possible disease risks to introduce better controls on such movements.*
- (2) *It is necessary to take into account in such cross-border movements the disease situation of Member States.*
- (3) *The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,*
HAS ADOPTED THIS DECISION:

2002/33/EC

- (1) Numerous Community acts lay down animal and public health conditions for the processing and disposal of animal waste and for the production, placing on the market, trade and importation of products of animal origin not intended for human consumption.
- (2) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down the health rules concerning animal by-products not intended for human consumption has replaced the rules contained in those acts.
- (3) To take account of those new rules, 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 and Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC, should therefore be amended,

HAVE ADOPTED THIS DIRECTIVE:

2003/42/EC

- (1) Specific public health conditions for the preparation of collagen intended for human consumption should be laid down. Provided that these conditions are the same for collagen intended for human consumption and collagen not intended for human consumption, and provided that hygiene conditions are also the same, it should be possible to produce and/or store both types of collagen in the same establishment.
- (2) The authorisation and registration, inspection and hygiene conditions for the establishments preparing collagen should be set. Certain health conditions contained in Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the production and marketing of meat products and certain other products of animal origin, as last amended by Directive 97/76/EC, and in Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs, are relevant for the preparation of collagen.
- (3) Article 2.3.13.7 of the International Animal Health Code (2001) issued by the International Office of Epizootics on BSE recommends that if gelatine and collagen are prepared exclusively from hides and skins, veterinary administrations should authorise their import and transit through their territories without restriction, regardless of the status of the exporting countries.
- (4) Under Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, as last amended by Commission Regulation (EC) No 1494/2002, hides and skins within the meaning of Directive 92/118/EEC, derived from healthy ruminants and collagen derived from such hides and skins are not subject to restrictions on placing on the market.
- (5) The Scientific Steering Committee adopted an opinion on the safety of collagen on 10 and 11 May 2001, addressing the question of the safety in relation to transmissible spongiform encephalopathies (hereinafter TSE) of collagen produced from ruminant hides.
- (6) The raw material used for the production of collagen consists mainly of bovine connective tissue of hides and tendons, calf skins, sheep skins and pig skins. To ensure the safety of the raw material, it must derive from animals that pass ante and post-mortem inspections as fit for human consumption. Such material must also be collected, transported, stored and handled in the most hygienic ways possible.
- (7) To guarantee traceability of the raw material, collection centres and tanneries, which intend to supply the raw material, should be authorised and registered. A model commercial document should also be prescribed to accompany the raw material during transportation and at time of delivery to the collection centres, tanneries and collagen processing plants.
- (8) It is appropriate to amend the current commercial document for raw material destined for the production of gelatine for human consumption, to take into account particulars in relation to control procedures in certain Member States.
- (9) The standards for the finished product should be fixed to ensure that it is not contaminated with substances or micro-organisms presenting a risk to consumer health. Pending a scientific evaluation of such standards, it is appropriate to include, on a provisional basis, generally accepted standards as regards contamination. The requirements for packaging, storage and transport of the finished product should also be laid down.
- (10) It is necessary to lay down specific health rules for the importation of collagen and raw material destined for the production of collagen intended for human consumption. Specimens of health certificates to accompany the imported collagen and raw material destined for the production of collagen for human consumption should be drawn up. It is also necessary for the Commission to recognise conditions offering equivalent guarantees based on a proposal submitted by a third country.
- (11) The adoption of specific rules for the production of collagen should be without prejudice to the adoption of rules for the prevention and control of TSE.
- (12) Directive 92/118/EEC should therefore be amended accordingly.
- (13) 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:

2003/721/EC

- (1) Specific public health conditions for the preparation of collagen intended for human consumption should be laid down. Provided that these conditions are the same for collagen intended for human consumption and collagen not intended for human consumption, and provided that hygiene conditions are also the same, it should be possible to produce and/or store both types of collagen in the same establishment.
- (2) The authorisation and registration, inspection and hygiene conditions for the establishments preparing collagen should be set. Certain health conditions contained in Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the production and marketing of meat products and certain other products of animal origin, as last amended by Regulation (EC) No

807/2003, and in Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs ⁽⁵⁾, are relevant for the preparation of collagen.

- (3) Article 2.3.13.7 of the International Animal Health Code (2001) issued by the International Office of Epizootics on BSE recommends that if gelatine and collagen are prepared exclusively from hides and skins, veterinary administrations should authorise their import and transit through their territories without restriction, regardless of the status of the exporting countries.
- (4) Under Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, as last amended by Commission Regulation (EC) No 1234/2003, hides and skins within the meaning of Directive 92/118/EEC, derived from healthy ruminants and collagen derived from such hides and skins are not subject to restrictions on placing on the market.
- (5) The Scientific Steering Committee adopted an opinion on the safety of collagen on 10 and 11 May 2001, addressing the question of the safety in relation to transmissible spongiform encephalopathies (hereinafter TSE) of collagen produced from ruminant hides.
- (6) The raw material used for the production of collagen consists mainly of bovine connective tissue of hides and tendons, calf skins, sheep skins and pig skins. To ensure the safety of the raw material, it must derive from animals that pass ante and post mortem inspections as fit for human consumption. Such material must also be collected, transported, stored and handled in the most hygienic ways possible.
- (7) To guarantee traceability of the raw material, collection centres and tanneries, which intend to supply the raw material, should be authorised and registered. A model commercial document should also be prescribed to accompany the raw material during transportation and at time of delivery to the collection centres, tanneries and collagen processing plants.
- (8) It is appropriate to amend the current commercial document for raw material destined for the production of gelatine for human consumption, to take into account particulars in relation to control procedures in certain Member States.
- (9) The standards for the finished product should be fixed to ensure that it is not contaminated with substances or micro-organisms presenting a risk to consumer health. Pending a scientific evaluation of such standards, it is appropriate to include, on a provisional basis, generally accepted standards as regards contamination. The requirements for packaging, storage and transport of the finished product should also be laid down.
- (10) It is necessary to lay down specific health rules for the importation of collagen and raw material destined for the production of collagen intended for human consumption. Specimens of health certificates to accompany the imported collagen and raw material destined for the production of collagen for human consumption should be drawn up. It is also necessary for the Commission to recognise conditions offering equivalent guarantees based on a proposal submitted by a third country.
- (11) The adoption of specific rules for the production of collagen should be without prejudice to the adoption of rules for the prevention and control of TSE.
- (12) Directive 92/118/EEC should therefore be amended accordingly.
- (13) Decision 2003/42/EC amended Directive 92/118/EEC, with effect from 30 September 2003, as regards the specific health conditions for collagen intended for human consumption and certification requirements for collagen and raw material for collagen production, intended for dispatch to the European Community for human consumption.
- (14) The Community imports from third countries raw material and collagen, including collagen meeting certain technical requirements which is not available in the Community.
- (15) The United Kingdom has requested a postponement of the application of the new specific health conditions to enable account to be taken of its producers who are dependent on imports from third countries.
- (16) The negotiations to find a resolution to problems in relation to imports of collagen aimed at allowing such imports to continue in full compliance with the new specific health conditions can now be considered concluded.
- (17) It is appropriate to allow time for the conclusion of the administrative steps of those negotiations but that period should be as short as possible.
- (18) An error has been found in the Annex to Decision 2003/42/EC in that the commercial document model for raw material destined for the production of collagen unintentionally requires a stamp of an official veterinarian. That error should be corrected.
- (19) For the sake of clarity, Decision 2003/42/EC should therefore be repealed and replaced by the present Decision.
- (20) 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:

(EC) No 445/2004

- (1) Directive 92/118/EEC sets out Community rules concerning animal and public health requirements governing trade in and importation into the Community of products of animal origin.
- (2) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption, as last amended by Commission Regulation (EC) No 808/2003, sets out Community rules on animal products not intended for human consumption.
- (3) Directive 2002/33/EC of the European Parliament and of the Council of 21 October 2002 amending Council Directives 90/425/EEC and 92/118/EEC as regards health requirements for animal by-products, significantly amended Directive 92/118/EEC, in particular in order to reduce its scope so that it only covered animal products intended for human consumption and pathogens.
- (4) In the interests of clarity of Community legislation, it is appropriate to further clarify the scope of Directive 92/118/EEC.
- (5) Directive 92/118/EEC should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER I **General provisions**

Article 1

This Directive lays down the animal health and public health requirements governing trade in and imports into the Community of products of animal origin (including trade samples taken from such products) not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogenic agents, to Directive 90/425/EEC.

This Directive shall be without prejudice to the adoption of more detailed rules on animal health in the framework of the aforesaid specific rules nor the maintenance of restrictions on trade or imports of products covered by the specific rules referred to in the first paragraph based on the rules of public health.

Article 2

1. For the purposes of this Directive:
 - (a) trade means trade as defined by Article 2 (2) of Directive 89/662/EEC;
 - (b) trade sample means a sample of no commercial value, taken on behalf of the owner or the person responsible for an establishment, which is representative of a given product of animal origin produced by that establishment, or constitutes a specimen of a product of animal origin the manufacture of which is contemplated, and which, for the purposes of subsequent examination, must bear a reference to the type of product, its composition and the species of animal from which it was obtained;
 - (c) serious transmissible disease means all diseases covered by Directive 82/894/EEC;
 - (d) pathogenic agents means any collection or culture of organisms or any derivative, present either alone or in the form of a manipulated combination of such a collection or culture of organisms capable of causing disease in any living being (other than man) and any modified derivatives of these organisms, which can carry or transmit an animal pathogen, or the tissue, cell culture, secretions or excreta by which or by means of which an animal pathogen can be carried or transmitted; this definition does not include the immunological veterinary medicinal products authorized pursuant to Directive 90/677/EEC;
 - (e) deleted by 2002/33/EC
 - (f) processed animal protein intended for human consumption means greaves, meatmeal and pork-rind powder referred to in Article 2 (b) of Directive 77/99/EEC;
 - (g) deleted by 2002/33/EC
2. In addition, the definitions contained in Article 2 of Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (Note by MediaLex: since 1 July 1999, Council Directive 97/78/EC, of 18.12.1997) shall apply mutatis mutandis.

Article 3

Member States shall ensure that:

- trade in and imports of products of animal origin referred to in Article 1 are not prohibited or restricted for animal health or public health reasons other than those arising from the application of this Directive or from Community legislation, and in particular any safeguard measures taken,
- any new product of animal origin intended for human consumption whose placing on the market in a Member State is authorised after the date provided for in Article 20 may not be the subject of trade or importation until a decision has been taken in accordance with the first paragraph of Article 15 after evaluation, if appropriate in the light of the opinion of the Scientific Veterinary Committee set up by Decision 81/651/EEC, of the real risk of the spread of serious transmissible diseases which could result from movement of the product, not only for the species from which the product originates but also for other species which could carry the disease, become a focus of disease or a risk to human health,
- the other products of animal origin referred to in Article 2 (b) of Directive 77/99/EEC may not be the subject of trade or importation from third countries unless they meet the requirements of that Directive and the relevant requirements of this Directive.

CHAPTER II
Provisions applicable to trade

Article 4

Member States shall take the necessary measures to ensure that, for the purposes of applying Article 4 (1) of Directive 89/662/EEC and Article 4 (1) (a) of Directive 90/425/EEC, the products of animal origin referred to in Annexes I and II and the second and third indents of Article 3 of this Directive may, without prejudice to the particular provisions to be adopted in implementation of Articles 10 (3) and 11, be the subject of trade only if they satisfy the following requirements:

1. they must meet the requirements of Article 5 and the specific requirements laid down in Annex I as regards animal health aspects and Annex II as regards public health aspects,
2. they must come from establishments which:
 - (a) undertake, in the light of the specific requirements laid down in Annexes I and II for the products the establishment produces, to:
 - comply with the specific production requirements set out in this Directive,
 - establish and implement methods of monitoring and checking the critical points on the basis of the processes used,
 - depending on the products, take samples for analysis in a laboratory recognized by the competent authority for the purpose of checking compliance with the standards established by this Directive,
 - keep a record, whether written or otherwise recorded, of the information obtained pursuant to the preceding indents for presentation to the competent authority. The results of the various checks and tests in particular shall be kept for at least two years,
 - guarantee the administration of marking and labelling,
 - should the result of the laboratory examination or any other information available to them reveal the existence of a serious animal health or public health hazard, inform the competent authority,
 - consign, for purposes of trade, only products accompanied by a commercial document indicating the nature of the product, the name and, where appropriate, the veterinary approval number of the establishment of production;
 - (b) they are under supervision by the competent authority to ensure that the operator or manager of the establishment complies with the requirements of this Directive;
 - (c) they were registered by the competent authority on the basis of assurances from the establishment guaranteeing compliance with the requirements of this Directive.

Article 5

Member States shall ensure that every necessary measure is taken to guarantee that products of animal origin referred to in Annexes I and II are not dispatched for purposes of trade from any holding, situated in a zone subject to restrictions because of the occurrence of a disease to which the species from which the product is derived is susceptible or from any establishment or zone from which movements or trade would constitute a risk to the animal health status of the Member States except where products are heat-treated in accordance with Community legislation.

Particular assurances permitting, by way of derogation from the first paragraph, the movement of certain products may be adopted under the procedure laid down in Article 18 within the framework of safeguard measures.

Article 6

Member States shall ensure that trade in pathogenic agents is subject to strict rules to be defined under the procedure laid down in Article 18.

Article 7

1. The rules on checks established by Directive 89/662/EEC and, as regards pathogenic agents, by Directive 90/425/EEC shall apply, in particular as regards the organization of and follow-up to the checks to be carried out, to the products covered by this Directive.
2. Article 10 of Directive 90/425/EEC shall apply to the products covered by this Directive.
3. For the purposes of trade, the provisions of Article 12 of Directive 90/425/EEC shall be extended to establishments supplying products of animal origin covered by this Directive.

4. Without prejudice to the specific provisions of this Directive, the competent authority shall carry out any checks it may deem appropriate where it is suspected that this Directive is not being complied with.
5. Member States shall take the appropriate administrative or penal measures to penalize any infringement of this Directive, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the products referred to in Annexes I and II, or that the products in question do not satisfy the requirements of this Directive or have not undergone the checks provided for therein.

Article 8

In Chapter 1 (1) of Annex A to Directive 92/46/EEC the following subparagraph is added:

'Milk and milk products must not come from a surveillance zone defined in accordance with Directive 85/511/EEC unless the milk has undergone pasteurization (71,7 °C for 15 seconds) under the supervision of the competent authority.'

CHAPTER III *Provisions applicable to imports into the Community*

Article 9

The requirements applicable to imports of products covered by this Directive must offer at least the guarantees provided for in Chapter II, including those established in implementation of Article 6, and those laid down in the second and third indents of Article 3.

Article 10

1. For the purposes of uniform application of Article 9, the following provisions shall apply.
2. The products referred to in Annexes I and II and in the second and third indents of Article 3 may be imported into the Community only if they satisfy the following requirements:
 - (a) unless otherwise specified in Annexes I and II, they must come from a third country or part of a third country on a list to be drawn up and updated in accordance with the procedure provided for in Article 18;
 - (b) unless otherwise specified in Annex II, products must come from establishments on a Community list to be drawn up in accordance with the procedure laid down in Article 18;
 - (c) in the cases specifically provided for in Annexes I and II and in the second and third indents of Article 3, they must be accompanied by an animal health or public health certificate corresponding to a specimen to be drawn up under the procedure provided for in Article 18, certifying that the products meet the additional conditions or offer the equivalent guarantees referred to in paragraph 3 (a) and come from establishments offering such guarantees, and signed by an official veterinarian or, as appropriate, by any other competent authority recognized under the same procedure.
3. Under the procedure provided for in Article 18:
 - (a) specific requirements shall be established - in particular for the protection of the Community from certain exotic diseases or diseases transmissible to man - or guarantees equivalent to those conditions.
The specific requirements and equivalent guarantees established for third countries may not be more favourable than those laid down in Annexes I and II and in the second and third indents of Article 3;
Pending the fixing of the detailed rules of application provided for in the fourth and fifth indents of Chapter 2 of Annex II, Member States shall ensure that imports of products referred to therein are subject to compliance with the minimum guarantees laid down in the said indents.
 - (b) deleted
 - (c) the nature of any treatment or the measures to be taken to avoid recontamination of animal casings, eggs and egg products shall be established.
4. The decisions provided for in paragraphs 2 and 3 must be taken on the basis of evaluation and, if appropriate, the opinion of the Scientific Veterinary Committee, of the real risk of the spread of serious transmissible diseases or of diseases transmissible to man which could result from movement of the product, not only for the species from which the product originates but also for other species which could carry the disease or become a focus of disease or a risk to public health.
5. Experts from the Commission and the Member States shall carry out on-the-spot inspections to verify whether the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the Community.

The experts from the Member States responsible for these inspections shall be appointed by the Commission, acting on proposals from the Member States.

These inspections shall be made on behalf of the Community, which shall bear the cost of any expenditure involved. Pending organization of the inspections referred to in the first subparagraph, national rules applicable to inspection in third countries shall continue to apply, subject to notification, through the Standing Veterinary Committee, of any failure to comply with the guarantees offered in accordance with paragraph 3 found during these inspections.

6. Pending compilation of the lists provided for in paragraphs 2 (a) and (b) second indent, Member States are authorized to maintain the controls provided for in Article 11 (2) of Directive 90/675/EEC (Note by MediaLex: since 1 July 1999, Council Directive 97/78/EC, of 18.12.1997) and the national certificate required by products imported under existing national rules.

Article 11

The procedure provided for in Article 18 shall be used to stipulate specific animal health requirements for imports into the Community and the nature and content of accompanying documents for products referred to in Annex I intended for experimental laboratories.

Article 12

1. The principles and rules laid down in Directives 90/675/EEC (Note by MediaLex: since 1 July 1999, Council Directive 97/78/EC, of 18.12.1997) and 91/496/EEC shall apply, with particular reference to the organization of and follow-up to the inspections to be carried out by the Member States and the safeguard measures to be implemented. However, for certain types of product of animal origin, derogations may be adopted in accordance with the procedure laid down in Article 18, from the physical check provided for in Article 4 (4) (b) of directive 97/78/EC.

Article 13

1. Member States may, by issuing an appropriate licence, permit the importation from third countries of products of animal origin referred to in Annexes I and II in the form of trade samples.
2. The licence mentioned in paragraph 1 must accompany the consignment and contain full details of the specific conditions under which the consignment may be imported, including any derogations from the checks provided for by Directive 90/675/EEC (Note by MediaLex: since 1 July 1999, Council Directive 97/78/EC, of 18.12.1997).
3. Where the consignment enters one Member State for onward transmission to a second Member State, the first Member State shall ensure that the consignment is accompanied by the appropriate licence. Movement shall take place in accordance with the provisions of Article 11 (2) of Directive 90/675/EEC (Note by MediaLex: since 1 July 1999, Council Directive 97/78/EC, of 18.12.1997). The responsibility for ensuring that the consignment complies with the conditions of the licence (and whether entry into its territory should be permitted) shall rest with the Member State which issues the licence.

CHAPTER IV

Common final provisions

Article 14

1. Article 3 (d) of Directive 72/461/EEC shall be deleted. Commission Decisions 92/183/EEC and 92/187/EEC shall continue to apply for the requirements of this Directive, without prejudice to any amendments to be made to them under the procedure provided for in Article 18.
2. Directive 90/667/EEC is hereby amended as follows:
 - (a) in Article 13 the following paragraph shall be added:
 - '2. With a view to ensuring that the controls provided for in paragraph 1 are followed up:
 - (a) processed products obtained from low-risk or high-risk materials must satisfy the requirements of Chapter 6 of Annex I to Directive 92/118/EEC();
 - (b) low-risk materials, high-risk materials intended for processing in a plant designated in another Member State in accordance with the second sentence of Article 4 (1) and processed products obtained from high-risk or low-risk materials must be accompanied:
 - if they come from a plant approved in accordance with Article 4 or 5, by a commercial document specifying;
 - if appropriate, the nature of the treatment,
 - whether the product contains ruminant proteins,
 - if they come from another plant, by a certificate issued and signed by an official veterinarian indicating:

- the methods of treatment used on the consignment,
 - the result of the salmonella tests,
 - whether the product contains ruminant proteins.
- (b) in Article 6, 'shall be established under the procedure laid down in Article 19' shall be replaced by 'are laid down under Chapter 10 of Annex I to Directive 92/118/EEC';
- (c) in Article 14 the first paragraph shall be deleted.

Article 15

The Council, acting by a qualified majority on a proposal from the Commission, shall adopt any new Annex laying down specific requirements for other products capable of presenting a real risk of spreading serious transmissible diseases or a real risk to human health.

The Annexes shall, where the need arises, be amended under the procedure provided for in Article 18 in compliance with the general principles set out in the second indent of Article 3.

Article 16

1. Member States shall be authorized to make the entry into their territory of products of animal origin referred to in Annexes I and II and in the second and third indents of Article 3 which were produced in the territory of a Member State and have passed through the territory of a third country subject to production of an animal health or public health certificate certifying compliance with the requirements of this Directive.
2. Member States which have recourse to the possibility laid down in paragraph 1 shall so inform the Commission and the other Member States within the Standing Veterinary Committee set up by Decision 68/361/EEC.

Article 17

1. Annexes A and B to Directives 89/662/EEC and 90/425/EEC shall be replaced by the texts set out in Annex III to this Directive.
2. Directive 77/99/EEC is hereby amended as follows:
 - in Article 2 (b), point (iv) shall be deleted and points (v) and (vi) shall become (iv) and (v) respectively;
 - Article 6 (2) shall read:

'2. Under the procedure laid down in Article 20, additional conditions may be set for the other products of animal origin so as to ensure the protection of public health.'

Article 18

Where reference is made to the procedure provided for in this Article, the Standing Veterinary Committee shall act in accordance with the rules laid down in Article 17 of Directive 89/662/EEC.

Article 19

Under the procedure provided for in Article 18, transitional measures may be adopted for a period of up to three years beginning on 1 July 1993 to facilitate the transition to the new arrangements established by this Directive.

Article 20

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 12 (2) and 17 by 1 January 1993 and with the other requirements of this Directive before 1 January 1994. They shall forthwith inform the Commission thereof.

When these measures are adopted by the Member States, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.
2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.
3. The setting of the deadline for transposition into national law at 1 January 1994 shall be without prejudice to the abolition of veterinary checks at frontiers provided for by Directives 89/662/EEC and 90/425/EEC.

Article 21

This Directive is addressed to the Member States.

Done at Brussels, 17 December 1992.

ANNEX I

SPECIFIC ANIMAL HEALTH REQUIREMENTS

CHAPTER 1 *deleted by 2002/33/EC*

CHAPTER 2

Animal casings*

Animal casings intended for human consumption**

A. Trade

Trade in animal casings is subject to production of a document specifying the plant of origin which must be:

- where the casings are salted or dried at the point of origin and where salted or dried casings are subsequently handled for other purposes, a plant approved by the competent authority,
- in other cases, a plant approved in accordance with Directive 64/433/EEC, provided the casings are transported in such a way as to avoid contamination.

B. Imports from third countries

Imports of animal casings from any third country are subject to production of the certificate referred to in Article 10 (2) (c), issued and signed by an official veterinarian of the exporting third country, stating that:

- (i) the casings come from plants approved by the competent authority of the exporting country;
- (ii) the casings have been cleaned, scraped and then either salted or bleached (or as an alternative to salting or bleaching, that they have been dried after scraping);
- (iii) after the treatment in (ii), effective steps were taken to prevent the recontamination of the casings.

CHAPTER 3 *deleted by 2002/33/EC*

CHAPTER 4 *deleted by 2002/33/EC*

CHAPTER 5

Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) intended for human consumption

Trade in and imports of the products in question are subject to the following conditions:

1. where trade is concerned, bones, horns and hooves are subject to the animal health requirements laid down in Directive 72/461/EEC;
2. where trade is concerned, bone products, horn products and hoof products are subject to the animal health requirements provided for in Directive 80/215/EEC;
3. where imports are concerned, bones, bone products, horns, horn products, hooves and hoof products are subject to the requirements of Directive 72/462/EEC;

CHAPTER 6

Processed animal protein intended for human consumption

- I. Without prejudice to any restrictions imposed as regards BSE or to the restrictions on the feedings of ruminant protein to ruminants, trade in and imports of processed animal protein are subject:
 - A. As regards trade, to the production of the document or certificate provided for in Directive 77/99/EEC, stating that the requirements of that Directive have been complied with;

- B. as regards imports:
1. to production of a health certificate as provided for in Article 10(2) (c), signed by the official veterinarian of the country of origin and stating that:
 - (a) the products fulfil the requirements of Directive 80/215/EEC;
 - (b) every precaution has been taken after treatment to prevent contamination of the product treated;
 - (c) samples have been taken and tested for salmonella when the consignment left the country of origin;
 - (d) the results of these tests are negative;
 2. following document checks of the certificate referred to in 1, to sampling by the competent authority at the border inspection post without prejudice to point II:
 - (i) of each consignment of products submitted in bulk;
 - (ii) at random of consignments of products packaged in the manufacturing plant;
 3. for release for free circulation in Community territory of consignments of processed animal protein, to prove that the results of the sampling carried out pursuant to B (1) (c) have proved negative, if necessary after reprocessing;
- C. national rules existing on the date of notification of this Directive concerning the requirements applicable as regards BSE and scrapie for animal proteins may be maintained pending a decision on the type of heat treatment capable of destroying the agent responsible.

Trade in and imports of meat meal and bone meal remain subject to Article 5 (2) of Directive 89/662/EEC and Article 11 (2) of Directive 90/675/EEC (Note by MediaLex: since 1 July 1999, Council Directive 97/78/EC, of 18.12.1997).

- II. Member States may carry out random sampling of bulk consignments originating in a third country from which the last six consecutive tests have proved negative. Where during one of these checks a result has proved positive, the competent authority of the country of origin must be informed so that it can take appropriate measures to remedy the situation. These measures must be brought to the attention of the competent authority responsible for the import checks. In the event of a further positive result from the same source, further tests must be carried out on all consignments from the same source until the requirements laid down in the first sentence are again satisfied.
- III. Member States must keep records of the results of sampling carried out on all consignments which have undergone sampling.
- IV. In accordance with Article 3 (3) of Directive 89/662/EEC, transshipment of consignments is permitted only through ports which have been approved under the procedure laid down in Article 18, provided that a bilateral agreement has been reached between Member States to allow checking of the consignments to be deferred until they reach the border inspection post of the Member State of final destination.
- V. Where a consignment proves to be positive for salmonella, it is either:
 - (a) re-exported from the Community;
 - (b) used for purposes other than animal feeds. In this case, the consignment may leave the port or storage depot only on condition that it is not incorporated into animal feedingstuffs;
 - (c) re-processed in a treatment plant approved pursuant to Directive 90/667/EEC or any plant approved for decontamination. Movement from the port or storage depot shall be controlled by permit from the competent authority and the consignment shall not be released until it has been treated, tested for salmonella by the competent authority in accordance with Annex II, Chapter III, to Directive 90/667/EEC and a negative result obtained.

CHAPTER 7

Blood and blood products of ungulates and poultry (with the exception of serum from equidae)

- I. Fresh blood and blood products intended for human consumption
 - A. Trade
 1. Trade in fresh blood of ungulates and poultry intended for human consumption is subject to the animal health conditions applicable to trade in fresh meat pursuant to Council Directives 72/461/EEC, 91/494/EEC or 91/495/EEC.
 2. Trade in blood products intended for human consumption is subject to the animal health conditions laid down in Chapter 11 of this Directive.
 - B. Imports

1. Imports of fresh blood of domestic ungulates intended for human consumption are prohibited pursuant to Council Directive 72/462/EEC.
Imports of fresh blood of domestic poultry intended for human consumption are subject to the animal health conditions laid down in Directive 91/494/EEC.
Imports of fresh blood of reared game intended for human consumption are subject to the animal health conditions laid down in Chapter 11 of this Annex.
2. Imports of blood products for human consumption, including those referred to in Council Directive 77/99/EEC, are subject to the animal health conditions applicable to meat products pursuant to Directive 72/462/EEC and this Directive, without prejudice to the rules on blood-based processed animal protein products referred to in Chapter 6 of this Annex.

II. deleted by 2002/33/EC

III. General provisions

The detailed rules for the application of this Chapter are to be adopted, where necessary, in accordance with the procedure laid down in Article 18.

CHAPTER 8
deleted by 2002/33/EC

CHAPTER 9

*Lard and rendered fats**

*Lard and rendered fats intended for human consumption***

1. Member States shall authorize the importation into the Community of lard and rendered fats from third countries appearing on the list annexed to Decision 79/542/EEC from which the importation of fresh meat of the species concerned is permitted.
2. Where there has been an outbreak of a serious transmissible disease in the previous 12 months before export in a country mentioned in paragraph 1, each consignment of lard or rendered fats must be accompanied by a certificate referred to in Article 10 (2) of this Directive stating that:
 - A. the lard or rendered fats have been subjected to one of the following heat treatment processes:
 - (i) at least 70 °C for at least 30 minutes; or
 - (ii) at least 90 °C for at least 15 minutes; or
 - (iii) a minimum temperature of 80 °C in a continuous rendering system;
 - B. where the lard or rendered fats are packaged, they have been packed in new containers and all precautions have been taken to prevent their recontamination;
 - C. where bulk transport of the product is intended, the pipes, pumps and bulk tank and any other bulk container tanks or bulk road tanker used in the transportation of the products from the manufacturing plant either directly on to the ship or into shore tanks or direct to establishments were inspected and found to be clean before use.

CHAPTER 10
deleted by 2002/33/EC

CHAPTER 11

*Rabbit meat and farmed game meat**

*Rabbit meat and farmed game meat intended for human consumption***

Member States shall ensure that rabbit meat and farmed game meat are imported only if:

- (a) they come from third countries included:
 - (i) for furred farm game, on the list of countries from which fresh meat of the corresponding species may be imported pursuant to Directive 72/462/EEC;
 - (ii) for feather farmed game, on the list of countries from which fresh poultrymeat may be imported pursuant to Directive 91/494/EEC;

- (iii) for rabbit meat, on a list to be drawn up under the procedure laid down in Article 18;
- (b) they satisfy at least the requirements laid down in Chapters II and III respectively of Directive 91/495/EEC;
- (c) they come from establishments offering the guarantees provided for in (b) and recognized under the procedure provided for in Article 18 or, pending the list referred to in (a) (iii), from establishments approved by the competent authorities;
- (d) each batch of meat is accompanied by the health certificate provided for in Article 10 (2) (c).

CHAPTER 12
deleted by 2002/33/EC

CHAPTER 13
deleted by 2002/33/EC

CHAPTER 14
deleted by 2002/33/EC

CHAPTER 15
deleted by 2002/33/EC

* Note by MediaLex: Valid till 01.May 2004

** Note by MediaLex: Valid from 01.May 2004

ANNEX II

SPECIFIC PUBLIC HEALTH CONDITIONS

CHAPTER 1

Imports from third countries of meat products obtained from poultrymeat, farmed game meat, wild game meat and rabbit meat Member States shall ensure that meat products obtained from poultrymeat, farmed game meat, wild game meat and rabbit meat are not imported unless:

- a) either they come from a third country listed in accordance with:
 - (i) Article 9 of Directive 91/494/EEC for poultrymeat;
 - (ii) Article 16 of Directive 92/45/EEC for wild game meat;
 - (iii) Chapter 2 of Annex I to this Directive for rabbit meat and farmed-game meateither they come from a third country listed in the Annex, Part I of Decision 79/542/EEC. In this case they must have undergone a heat treatment in a sealed container, the Fo value being equal or over 3,00. However, for meat products made from species other than swine, this treatment may be replaced by a heat treatment which brings the internal temperature to at least 70°C
- (b) the fresh meat used meets the appropriate requirements of Article 14 of Directive 71/118/EEC for poultrymeat, Article 16 of Directive 92/45/EEC for wild game meat, Article 3 of Directive 91/495/EEC for rabbit meat and Article 6 of that Directive for farmed-game meat;
- (c) they come from an establishment offering the same guarantees as those referred to in Directive 77/99/EEC and approved in accordance with the procedure provided for in Article 18 or, pending the adoption of such a decision, by the competent authority of the Member State with imports of these products remaining subject to the rules in Article 11 (2) of Directive 90/675/EEC (Note by MediaLex: since 1 July 1999, Council Directive 97/78/EC, of 18.12.1997);
- (d) they are prepared, checked and handled in accordance with the appropriate requirements provided for in Directive 77/99/EEC;
- (e) each consignment of meat products is accompanied by a health certificate established in accordance with the procedure provided for in Article 18.

CHAPTER 2

Before 1 July 1997, the health conditions applicable to the following shall be established in accordance with the procedure laid down in Article 18:

- putting on the market in and imports of eggs and imports of egg products intended for human consumption, without prejudice to the rules laid down within the framework of the common organization of the market,
In respect of salmonella and pending the adoption of Community provisions, the following rules shall apply for eggs intended for Finland, Norway and Sweden:
 - (a) consignments of eggs may be subject to additional general or limited guarantees defined by the Commission following the procedure provided for in Article 18;
 - (b) the guarantees provided for in (a) shall not be carried out for eggs originating in an establishment subject to a programme recognized as equivalent to that referred to in (c), pursuant to the procedure provided for in Article 18;
 - (c) the guarantees provided for in (a) shall apply only after approval by the Commission of an operational programme to be presented by Finland, Norway and Sweden. The Commission decisions must be taken before the date of entry into force of the Accession Treaty in order for the operational programmes and the guarantees provided for in (a) to be applicable as from the date of entry into force of the Accession Treaty
- trade in and import of honey, intended for human consumption.
 - trade in and imports of milk and milk-based products intended for human consumption, obtained from species not covered by Directive 92/46/EEC; depending on the species, specific requirements may be laid down as regards:
 - animal health and, the health status of dairy herds, in particular with regard to tuberculosis and brucellosis;
 - hygiene in respect of
 - milking,
 - the collection, transport, treatment and processing of milk,

- staff,
 - testing for residues of pharmacologically and/or hormonally active substances, antibiotics, pesticides or other harmful substances in milk or milk products,
 - criteria applicable to raw milk as a raw material,
 - microbiological criteria applicable to finished products,
 - the production, placing on the market and importation of meat of species not covered by specific requirements, and in particular reptile meat and products thereof, intended for human consumption.
- Depending on the species, specific requirements may be laid down as regards:
- microbiological and parasitological criteria,
 - hygiene during slaughter,
 - testing for residues.

CHAPTER 3

I. Specific public health conditions applicable to trade in and imports of snails intended for human consumption

- A.** Without prejudice to Community, national or international provisions on the protection of wildlife, for the purpose of this Chapter, 'snails' means terrestrial gastropods of the species *Helix pomatia* Linné, *Helix aspersa* Muller, *Helix lucorum* and species of the family of Achatinidae.
- B.** Member States must ensure that shelled, cooked and prepared or preserved snails are traded for human consumption only if they meet the following conditions:
- (1) They must come from establishments:
 - which meet the requirements of Article 4 (2) of this Directive,
 - which are approved by the competent authority in accordance with the requirements of Chapters III and IV of the Annex to Directive 91/493/EEC,
 - which undergo monitoring by the competent authority of production conditions and health checks in accordance with Chapter V (I) (3) and (5) and (II), (3) and (4) of Directive 91/493/EEC,
 - which conduct own checks in accordance with the provisions of Commission Decision 94/356/EC.
 - (2) They must be subjected to organoleptic checks carried out by sampling. If the organoleptic examination reveals that the snails are not fit for human consumption, measures must be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption.
 - (3) For the preparation of shelled snailmeat,
 - (a) depending on the scale of the operation, establishments must set aside special rooms or areas for:
 - the storage of packaging and wrapping materials,
 - the reception and storage of live snails,
 - washing, blanching or boiling, shelling and trimming,
 - the storage and, where necessary, cleaning and treatment of shells,
 - the heat treatment of the snailmeat, where necessary,
 - the wrapping or packaging of the snailmeat,
 - the storage of the finished product in cold stores;
 - (b) the snails must be checked before being boiled. Dead snails must not be prepared for human consumption;
 - (c) following shelling, the hepatopancreas removed during trimming must not be used for human consumption.
 - (4) Canned snails
Establishments must satisfy the conditions laid down in Chapter IV (IV) (4) of the Annex to Directive 91/493/EEC.
 - (5) Cooked and prepared snails
 - (a) Depending on the scale of the operation, establishments must set aside special rooms or areas for:
 - the storage of shelled snailmeat in cold stores,

- the storage of clean shells,
- the storage of breeding products,
- the preparation of stuffing,
- cooking and cooling,
- the filling of the shells with snailmeat and stuffing, and packaging in a controlled-temperature room,
- where applicable, freezing,
- the storage of finished products in cold stores;

Products must satisfy the relevant conditions set out in Chapter IX of Annex B to Directive 77/99/EEC.

- (b) Snailmeat used to fill shells prior to cooking must satisfy the conditions laid down in respect of shelled snailmeat.
- (6) In accordance with the procedure laid down in Article 18 of this Directive, microbiological criteria, including sampling plans and methods of analysis, may be laid down when there is a need to protect public health.
 - (7) The snails must be put up, packaged, stored and transported under the appropriate hygiene conditions laid down in Chapters VI and VIII of the Annex to Directive 91/493/EEC.
 - (8) The packaging and wrapping of snails must bear an identification mark containing the following particulars:
 - the name of the consigning country in capitals, or the initial letter or letters of the consigning country in printed capitals, i.e.: B, CZ, DK, D, EE, EL, E, F, IRL, I, CY, LV, LT, L, HU, MT, NL, AT, PL, P, SI, SK, FI, SE, UK followed by the approval number of the establishment, and one of the following sets of initials: CE, EC, EF, EG, EK, EY, ES, EÜ, EB, KE, WE.

C. For imports:

- (1) the packaging and wrapping of shelled, cooked and prepared or preserved snails must carry the name or ISO code of the country of origin and the approval number of the production establishment in indelible print;
- (2) the following is an example of the specimen health certificate laid down in Article 10 (2) (c) of this Directive, which must accompany every consignment of shelled, cooked and prepared or preserved snails originating in third countries.

SPECIMEN HEALTH CERTIFICATE

FOR SHELLED, COOKED, PREPARED OR PRESERVED SNAILS ORIGINATING IN THIRD COUNTRIES AND INTENDED FOR THE EUROPEAN COMMUNITY

Note to the importer: this certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection point.

Reference No:.....

Country of dispatch:.....

Competent authority:

I. Identification of snails

Description of product:

- species (scientific names):.....

- state⁽¹⁾ and nature of treatment:

Code No (as appropriate):.....

Type of packaging:

Number of packages:

Net weight:.....

Required storage and transportation temperature:

II. Origin of snails

Name(s) and official approval number(s) of establishment(s) approved by the competent authority for export to the European Community:

.....

.....

.....

III. Destination of products

The snails are dispatched from:

(place of dispatch)

to:.....

(country and place of destination)

by the following means of transport⁽²⁾:.....

Name and address of consignor:

.....

Name of consignee and address of the place of destination:

.....

IV. Health attestation

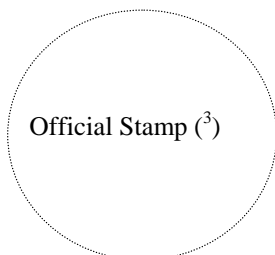
The undersigned official inspector hereby certifies that the snails described above:

- (1) have been handled and, where appropriate, shelled, cooked, prepared, preserved, frozen, packaged and stored in a hygienic manner in accordance with the requirements of Chapter 3 (I) of Annex II to Directive 92/118/EEC;

- (2) have been the subject of an own check programme drawn up and implemented by the person responsible for the establishment in accordance with Directive 94/356/EC;
- (3) have undergone an official health check in accordance with Chapter V of the Annex to Directive 91/493/EEC.

The undersigned official inspector hereby declares that he is aware of the provisions of Chapter 3, Part I, of Annex II to Council Directive 92/118/EEC, of the provisions of Chapters III, IV, V, VI and VII of Directive 91/493/EEC of the provisions of Chapter IX of Annex B to Directive 77/99/EEC and of the provisions of Decision 94/356/EC.

Done at on
(place) (date)



.....
(Name in capital letters signature of the official veterinarian)
(3)

(¹) Chilled, frozen, shelled, cooked, prepared, preserved.

(²) Registration number of lorries, railway wagons or container, flight number or name of ship.

(³) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

II. Specific public health conditions applicable to trade in and imports of frogs' legs intended for human consumption

- A.** Without prejudice to Community, national or international provisions on the protection of wildlife, for the purposes of this Chapter, 'Frogs' legs` means the back part of the body divided by a transversal cut behind the front limbs, eviscerated and skinned, of the species *Rana* spp. (family Ranidae), presented fresh, frozen or processed.
- B.** Member States must ensure that frogs' legs are traded for human consumption only if they meet the following conditions:
- (1) The frogs must have been slaughtered, bled, prepared and, where appropriate, chilled, frozen, processed, packaged and stored in establishments which:
 - meet the requirements of Article 4, point 2 of this Directive,
 - are approved by the competent authority in accordance with the requirements of Chapters III and IV of the Annex to Directive 91/493/EEC,
 - undergo monitoring by the competent authority of production conditions and health checks in accordance with Chapter V (I) (3) and (5) and (II) (3) and (4) of the Annex to Directive 91/493/EEC,
 - conduct own checks in accordance with the provisions of Decision 94/356/EC.
 - (2) The frogs legs must be subjected to organoleptic checks carried out by sampling. If the organoleptic examination reveals that the frogs legs are not fit for human consumption, measures must be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption.
 - (3) In addition, a special room must be set aside for the storage and washing of live frogs, and for their slaughter and bleeding. The death of frogs must only be carried out by slaughter in an approved establishment. Frogs which are found to be dead prior to slaughter must not be prepared for human consumption. The special room must meet the requirements of Chapter III, paragraph I, point 2 of the Annex to Directive 91/493/EEC and must be physically separated from the preparation room.
 - (4) Immediately following preparation, the frogs' legs must be washed very fully in running drinking water and immediately chilled at the temperature of melting ice, frozen at a temperature of at least -18°C or processed.
 - (5) Where the frogs' legs are processed, this must be carried out in accordance with the rules laid down in Chapter IV of the Annex to Directive 91/493/EEC.
 - (6) Microbiological controls In accordance with the procedure laid down in Article 18 of this Directive, microbiological criteria, including sampling plans and methods of analysis, may be laid down when there is a need to protect public health.
 - (7) The frogs' legs must be put up, packaged, stored and transported under the appropriate hygiene conditions laid down in Chapters VI and VIII of Directive 91/493/EEC.
 - (8) The packaging and containers of frogs' legs must bear an identification mark containing the following particulars:

The name of the consigning country in capitals, or the initial letter or letters of the consigning country in printed capitals, i.e.: B, CZ, DK, D, EE, EL, E, F, IRL, I, CY, LV, LT, L, HU, MT, NL, AT, PL, P, SI, SK, FI, SE, UK followed by the approval number of the establishment, and, one of the following sets of initials: CE, EC, EF, EG, EK, EY, ES, EÜ, EB, KE, WE.'
- C.** For imports:
- (1) The packaging and wrapping of frogs' legs must carry the name or ISO code of the country of origin and the approval number of the production establishment in indelible print.
 - (2) The following is an example of the specimen health certificate laid down in Article 10 (2) (c) of this Directive, which must accompany every consignment of frogs' legs originating in third countries:

SPECIMEN HEALTH CERTIFICATE

FOR CHILLED, FROZEN OR PREPARED FROGS' LEGS ORIGINATING IN THIRD COUNTRIES AND INTENDED FOR THE EUROPEAN COMMUNITY

Note to the importer: This certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection point.

Reference No:

Country of dispatch:

Competent authority:

I. Identification of frogs' legs

Description of product:

- species (scientific names):

- state⁽¹⁾ and nature of treatment:

Code No (as appropriate):

Type of packaging:

Number of packages:

Net weight:

Required storage and transportation temperature:

II. Origin of frogs' legs

Name(s) and official approval number(s) of establishment(s) approved by the competent authority for export to the European Community:

.....

.....

.....

.....

.....

III. Destination of products

The frogs' legs are dispatched from:

(Place of dispatch)

to:

(Country and place of destination)

by the following means of transport ⁽²⁾:

Name and address of consignor:

.....

Name of consignee and address of the place of destination:

.....

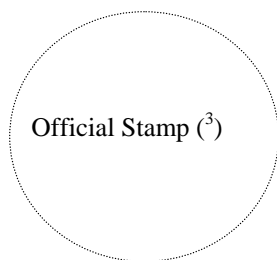
IV. Health attestation

The undersigned official inspector hereby certifies that the frogs' legs described above:

- (1) originate from frogs that have been bled, prepared and, where appropriate, chilled, frozen or processed, packaged and stored in a hygienic manner in accordance with the requirements of Chapter 3 (II) of Annex II to Directive 92/118/EEC;
- (2) have been the subject of an own check programme drawn up and implemented by the person responsible for the establishment in accordance with Decision 94/356/EC;
- (3) have undergone an official health check in accordance with the relevant provisions of Chapter V of the Annex to Directive 91/493/EEC.

The undersigned official inspector hereby declares that he is aware of the provisions of Chapter 3, Part II, of Annex II to Directive 92/118/EEC, of the provisions of Chapters II, IV, V, VI and VII of Directive 91/493/EEC and of the provisions of Decision 94/356/EC.

Done at on
 (place) (date)



.....
 (Name in capital letters signature of the official veterinarian)
 (3)

⁽¹⁾ Chilled, frozen, processed.

⁽²⁾ Registration number of lorries, railway wagons or container, flight number or name of ship.

⁽³⁾ The colour of the stamp and signature must be different from that of the other particulars in the certificate.

CHAPTER 4

SECTION A

SPECIFIC HEALTH CONDITIONS FOR THE GELATINE INTENDED FOR HUMAN CONSUMPTION

This chapter lays down the health conditions applicable to putting on the market and for imports of gelatine intended for human consumption, but excluding gelatine destined to pharmaceutical, cosmetic or other technical use and medical devices.

For the purpose of this chapter, the following definitions apply:

- gelatine: natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (including fish and poultry),
- hides and skins: all cutaneous and subcutaneous tissues,
- tanning: the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents,
- category 1 country or region: country or region classified as BSE free in accordance with Community legislation,
- category 2 country or region: country or region classified as provisionally BSE free with accordance to Community legislation,
- category 3 country or region: country or region classified as low BSE risk in accordance with Community legislation,
- category 4 country or region: country or region classified as high BSE risk in accordance with Community legislation.

Gelatine intended for human consumption shall comply with the following conditions:

1. CONDITIONS FOR ESTABLISHMENTS PRODUCING GELATINE

Gelatine intended for human consumption shall come from establishments which:

1. comply with the conditions laid down in Chapters I, II, V, VI, VII, VIII, IX and X of the Annex to Directive 93/43/EEC;
2. are authorised and registered in accordance with Article 11 of Directive 77/99/EEC;
3. are subject to supervision of production conditions by the competent authority in accordance with Chapter IV of Annex B to Directive 77/99/EEC as appropriate;
4. carry out an own-checks programme in accordance with Article 7(1) and (3) of Directive 77/99/EEC;
5. keep records for two years on the sources of all incoming raw material and on all outgoing products;
6. introduce and implement a system that makes it possible to link each production batch dispatched, the incoming raw material consignments, the production conditions and the time of production.

II. REQUIREMENTS FOR RAW MATERIALS TO BE USED FOR THE PRODUCTION OF GELATINE

1. For the production of gelatine intended for human consumption, the following raw materials may be used:
 - bones,
 - hides and skins of farmed ruminant animals,
 - pig skins,
 - poultry skin,
 - tendons and sinews,
 - wild game hides and skins,
 - fish skin and bones.
2. The use of bones obtained from ruminant animals born, reared or slaughtered in category 4 countries or regions is prohibited.
3. The use of hides and skins submitted to tanning processes is prohibited.

4. Raw materials listed in the first five indents of paragraph 1 shall be derived from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante and post mortem inspection.
5. Raw material listed in the sixth indent of paragraph 1 shall be derived from killed animals whose carcasses have been found fit for human consumption following the inspections laid down in Article 3 of Council Directive 92/45/EEC ⁽¹⁾
6. Raw materials listed in the first six indents of paragraph 1 shall come from slaughterhouses, cutting plants, meat processing establishments, wild game processing plants, bone degreasing plants, tanneries, collection centres, retail shops, or premises adjacent to sales points where the cutting and the storage of meat and poultrymeat is performed for the sole purpose of supplying the final consumer directly.
7. Raw material listed in the last indent of paragraph 1 shall come from plants manufacturing fish products for human consumption approved or registered in accordance with Council Directive 91/493/EEC ⁽²⁾
8. The collection centres and tanneries which intend to supply raw material for the production of gelatine intended for human consumption shall be specifically authorised for this purpose and registered by the competent authorities and fulfil the following requirements:
 - (a) they must have storage rooms with hard floors and smooth walls which are easy to clean and disinfect;
 - (b) where appropriate, they must be provided with refrigeration facilities;
 - (c) the storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials;
 - (d) if raw material not in conformity to this part is stored and/or processed in these premises, it must be segregated throughout the period of receipt, storage, processing and dispatch from raw material in conformity to this part;
 - (e) they must be inspected by the competent authority at regular intervals in order to ensure that this chapter is being complied with and to check accounting documents and/or health certificates which enable the origin of the raw material to be traced.
9. Imports into the Community of raw material destined to the production of gelatine intended for human consumption are subject to the following provisions:
 - Member States shall authorise the importation of this raw material only from third countries which appear on the list laid down in Council Decision 79/542/EEC⁽³⁾ or in Commission Decision 94/85/EC ⁽⁴⁾ or in Commission Decision 97/296/EC⁽⁵⁾ or in Decision 94/86/EC ⁽⁶⁾, as appropriate,
 - each consignment is accompanied by a certificate that conforms to the model laid down in accordance with the procedure provided for in Article 18 of this Directive.

III. TRANSPORT AND STORAGE OF RAW MATERIALS

1. Transports of raw materials destined to the production of gelatine must be carried out under clean conditions using appropriate means of transport.

During transportation, at the time of delivery in the collection centre and in the tannery and in the gelatine processing establishment, raw materials must be accompanied by a commercial document in conformity with the model laid down in Part VIII of this chapter.

2. Raw materials must be transported and stored chilled or frozen, unless they are processed within 24 hours after their departure.

By way of derogation from the preceding subparagraph, degreased and dried bones or ossein, salted, dried and limed hides and skins and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

3. The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.

IV. CONDITIONS TO BE COMPLIED WITH FOR THE MANUFACTURE OF GELATINE

1. Gelatine must be produced by a process which ensures that:
 - all ruminant bone material which is derived from animals born, reared and slaughtered in category 3 countries or regions is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4 % and pH < 1,5) over a period of at least two days, followed by an alkaline treatment of saturated lime solution (pH > 12,5) for a period of at least 20 days

with a sterilisation step of 138-140 °C during four seconds or by an equivalent process approved by the Commission after consultation of the appropriate Scientific Committee,

- other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.
2. After having been subjected to the processes listed in paragraph 1, gelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.
 3. The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.
 4. Provided the requirements for gelatine not intended for human consumption are exactly the same as for gelatine intended for human consumption, production and storage may be undertaken in the same establishment.

V. REQUIREMENTS FOR FINISHED PRODUCTS

Each production batch of gelatine shall be subjected to tests to ensure that it meets the following criteria:

1. Microbiological criteria

Microbiological parameters	Limit
Total aerobic bacteria	10 ³ /g
Coliforms (30°C)	0/g
Coliforms (44,5 °C)	0/10 g
Anaerobic sulphite-reducing bacteria (no gas production)	10/g
Clostridium perfringens	0/g
Staphylococcus aureus	0/g
Salmonella	0/25 g

2. Residues

Elements	Limit
As	1 ppm
Pb	5 ppm
Cd	0,5 ppm
Hg	0,15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
Moisture (105°C)	15%
Ash (550°C)	2%
SO ₂ (Reith Williems)	50 ppm
H ₂ =2 (European Pharmacopia 1986 (V ₂ O ₂))	10 ppm

VI. PACKAGING, STORAGE AND TRANSPORT

1. Gelatine intended for human consumption must be wrapped, packaged, stored and transported under satisfactory hygiene conditions, in particular:
 - a room must be provided for storing, wrapping and packaging materials,

- wrapping and packaging must take place in a room or in a place intended for that purpose.
- 2. Wrappings and packages containing gelatine must:
 - bear an identification mark giving the following particulars:
 - the name or initial letter or letters of the consigning country in printed capitals, i.e.: B-CZ-DK-D-EE-EL-E-F-IRL-I-CY-LV-LTL- HU-MT-NL-AT-PL-P-SI-SK-FI-SE-UK, followed by the registration number of the establishment and one of the following sets of initials: CE-EC-EF-EG-EK-EY-ES-EÜ-EB-KE-WE
 - and
 - carry the words "Gelatine for human consumption".
- 3. Gelatine must be accompanied during transportation by a commercial document, in accordance with Article 3(A)(9)(a) of Directive 77/99/EEC, which must bear the words "Gelatine for human consumption" and the date of preparation.

VII. IMPORTATION OF GELATINE FROM THIRD COUNTRIES

- A. Member States shall ensure that gelatine destined to human consumption is imported only if-
- it comes from third countries which appear on the list of Part XIII of the Annex to Commission Decision 94/278/EC⁽¹⁾,
 - it comes from establishments meeting the conditions laid down in Part 1 of this chapter,
 - it has been produced from raw material which met the requirements of Parts II and III of this chapter,
 - it has been manufactured in compliance with the conditions set out in Part IV of this chapter,
 - it satisfies the criteria of Part V and the requirements of part VI.1 of this chapter,
 - it bears on its wrappings and packages an identification mark giving the following particulars:
- the ISO Code reference of the country of origin followed by the registration number of the establishment and
- it is accompanied by a certificate that conforms to the model laid down in accordance with the procedure provided for in Article 18 of this Directive.
- B. In accordance with the procedure of Article 18 of this Directive, the Commission may recognise the health measures applied by a third country to the production of gelatine for human consumption, as offering guarantees equivalent to those applied for putting on the market in the Community, if the third country supplies objective proof in this respect.

When the Commission recognises such equivalence of the health measures of a third country, it shall adopt in accordance with the same procedure, the conditions governing the importation of gelatine for human consumption including the health certificate which must accompany the product.

⁽¹⁾ OJ L 268 L 268 14.9.1992, p.35

⁽²⁾ OJ L 268, 24.9.1991. p.15

⁽³⁾ OJ L 146, 14.6.1979, p.15

⁽⁴⁾ OJ L 44, 17.2.1994, p.31

⁽⁵⁾ OJ L 122, 14.5.1997, p.21

⁽⁶⁾ OJ L 44, 17.2.1994, p.33

VIII. MODEL OF COMMERCIAL DOCUMENT FOR RAW MATERIAL DESTINED TO THE PRODUCTION OF GELATINE FOR HUMAN CONSUMPTION

COMMERCIAL DOCUMENT

FOR RAW MATERIAL DESTINED TO THE PRODUCTION OF GELATINE FOR HUMAN CONSUMPTION

Number of the commercial document:

I. identification of the raw material

Nature of the raw material:

Raw material derived from the following animal species:

.....

Net weight:.....

identification mark (pallet or container):

II. Origin of the raw material (1):

Slaughterhouse

Address of the establishment:

Veterinary approval/registration number:

Cutting plant

Address of the establishment:.....

Veterinary approval/registration number:.....

Meat products plant

Address of the establishment:

Veterinary approval/registration number:

Other animal products plant

Address of the establishment:.....

Veterinary registration number*:

Registration number**:

Wild game processing establishment

Address of the establishment:.....

Veterinary approval number:.....

Fish products plants

Address of the establishment:.....

Veterinary approval/registration number:.....

Centres of collection

Address of the establishment:.....

Veterinary registration number*:

Registration number**:

Tannery

Address of the establishment:.....

Veterinary registration number*:

Registration number**:

Retailshop

Address:

Premises adjacent to sales points, where the cutting and the storage of meat and poultrymeat is performed for the sole purpose of supplying the final consumer directly

Address:

III. Destination of the raw material

The raw material will be sent to the following establishment (centre of collection/tannery/gelatine plant)⁽¹⁾:

Name:

Address:

IV. Declaration

I, the undersigned, declare that I read and understood the provisions of Part II and III of Chapter 4 of Annex 11 to Directive 92/118/EEC and that ⁽¹⁾:

- hides and skins from farmed ruminant animals, bones, pig skins, poultry skin and tendons and sinews described above are derived from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante and post mortem inspection

and/or

- hides and skins from wild game described above are derived from killed animals whose carcasses have been found fit for human consumption following the inspections laid down in Article 3 of Directive 92/45/EEC and/or
- fish skin and bones described above come from plants manufacturing fish products for human consumption or registered in accordance with Directive 91/493/EEC.

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

.....
(Signature of the owner of the plant or its representatives)

⁽¹⁾ Delete as appropriate

***) Note by MediaLex: Valid till 31.12.2003**

*****) Note by MediaLex: Valid from 31.12.2003. It shall not apply to collagen intended for human consumption that was produced or imported before that date.**

SECTION B*)
SPECIFIC HEALTH CONDITIONS FOR THE COLLAGEN INTENDED FOR HUMAN CONSUMPTION

I. General

1. This Section lays down the health conditions for putting on the market and imports of collagen intended for human consumption.
2. For the purposes of this Section, the definitions of “hides and skins” and “tanning” in section A shall apply.
The following definitions shall also apply:
 - (a) “collagen” means protein-based product derived from hides, skins and tendons of animals, including bones in the case of pigs, poultry and fish only, manufactured using the method set in Part V below.
 - (b) “collagen intended for human consumption” means collagen intended for consumption either as food or incorporated into or wrapped around food or product to be consumed by humans.
3. Collagen intended for human consumption shall comply with the conditions in Parts II to X below.

II. Establishments producing collagen

Collagen intended for human consumption shall come from establishments that fulfil the conditions in Part I of Section A.

III. Raw materials and establishments supplying them

1. The following raw materials may be used for the production of collagen intended for human consumption:
 - (a) hides and skins of farmed ruminant animals;
 - (b) pig skins, bones and intestines;
 - (c) poultry skin and bones;
 - (d) tendons;
 - (e) wild game hides and skins; and
 - (f) fish skin and bones.
2. The use of hides and skins submitted to tanning processes is prohibited.
3. The raw materials shall meet the following requirements:
 - for the raw materials listed in paragraph 1(a) to (d) above, the requirements set in Paragraph 4 of Part II of Section A apply;
 - for the raw material referred to in paragraph 1(e) above, the requirements set in Paragraph 5 of Part II of Section A apply;
 - for the raw materials listed in paragraph 1(a) to (e) above, the requirements set in Paragraph 6 of Part II of Section A apply, except that no raw material shall come from plants degreasing ruminant bones; and
 - for the raw material referred to in paragraph 1(f) above, the requirements set in Paragraph 7 of Part II of Section A apply.
4. The collection centres and tanneries supplying the raw material for the production of collagen intended for human consumption shall be specifically authorised for the purpose and registered by the competent authorities and fulfil the requirements set in Paragraph 8 of Part II of Section A.

IV. Transport and storage of the raw material

1. Transport and storage of the raw material destined for the production of collagen shall be done in accordance with Part III of Section A.
2. During transportation and at the time of delivery at the collection centres, tanneries and collagen processing plants, raw materials must be accompanied by a commercial document in conformity with the model laid down in Part IX of this Section.

V. Manufacture of collagen

1. Collagen must be produced by a process that ensures that the raw material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion; or by an equivalent process approved by the Commission after consultation of the appropriate Scientific Committee.
2. After having been subjected to the process referred to at paragraph 1 above, collagen may undergo a drying process.

3. Collagen not intended for human consumption may be produced and stored in the same establishment as collagen intended for human consumption only if it is produced and stored using exactly the same conditions set in this Section.
4. The use of preservatives other than those permitted under Community legislation is prohibited.

VI. Finished products

Appropriate measures, including tests shall be carried out to ensure that each production batch of collagen meets the microbiological and residues criteria set in Part V of Section A, but where necessary to achieve desired products such as collagen-based casings, no moisture and ash limit shall apply.

VII. Packaging, storage and transport

1. Collagen intended for human consumption must be wrapped, packaged, stored and transported under satisfactory hygiene conditions and, in particular, fulfil the conditions set in Paragraph 1 of Part VI of Section A.
2. Wrappings and packages containing collagen must bear an identification mark giving the particulars listed in the first indent of Paragraph 2 of Part VI of Section A, and carry the words “Collagen fit for human consumption” and the date of preparation and the batch number.
3. During transportation collagen must be accompanied by a commercial document, in accordance with Article 3(A)(9)(a) of Directive 77/99/EEC, bearing the words “Collagen fit for human consumption” and the date of preparation and the batch number.

VIII. Import from third countries of collagen and raw materials intended for the production of collagen for human consumption

1. Member States shall authorise import into the Community of collagen intended for human consumption only if it:
 - (a) comes from third countries listed in Part XIII of the Annex to Commission Decision 94/278/EC ⁽¹⁾;
 - (b) comes from establishments meeting the conditions laid down in Part II of this Section;
 - (c) has been produced from raw material that met the requirements of Parts III and IV of this Section;
 - (d) has been manufactured in compliance with the conditions set out in Part V of this Section;
 - (e) satisfies the criteria in Part VI and the wrapping, packaging, storage and transport conditions in Part VII(1) of this Section;
 - (f) bears on its wrappings and packages an identification mark giving the particulars specified in the sixth indent of Part VII(A) of Section A; and
 - (g) is accompanied by a health certificate that conforms to the model laid down in Part X(a) of this Section.
2. Member States shall authorise import into the Community of the raw material listed in Part III(1) of this Section for the production of collagen intended for human consumption only if:
 - (a) it comes from third countries listed in Council Decision 79/542/EEC ⁽²⁾ or in Commission Decision 94/85/EC ⁽³⁾ or in Decision 94/86/EC ⁽⁴⁾ or in Commission Decision 97/296/EC ⁽⁵⁾, as appropriate; and
 - (b) a health certificate conforming to the model laid down in Part X(b) of this Section accompanies each consignment of the raw material.
3. The health certificates referred to in paragraphs 1(g) and 2(b) above shall consist of one sheet, and shall be completed in at least one official language of the Member State through which the consignment first enters the Community, and in at least one official language of the Member State of destination.
4. The Commission may recognise, in accordance with the procedure of Article 18, the health measures applied by a third country for the production of collagen intended for human consumption as offering guarantees equivalent to those offered for putting collagen on the market in the Community, if the third country concerned supplies objective proof in this respect. When the Commission recognises such equivalence, it shall adopt in accordance with the same procedure, the conditions governing the importation of collagen for human consumption.

⁽¹⁾ OJ L 120, 11.5.1994, p. 44.

⁽²⁾ OJ L 146, 14.6.1979, p. 15.

⁽³⁾ OJ L 44, 17.2.1994, p. 31.

⁽⁴⁾ OJ L 44, 17.2.1994, p. 33.

⁽⁵⁾ OJ L 122, 14.5.1997, p. 21.

***) Note by MediaLex: Section B is valid from 31.12.2003 It shall not apply to collagen intended for human consumption that was produced or imported before that date.**

IX. Commercial document model
for raw material destined for the production of collagen intended for human consumption

Commercial document number:

1. Identification of the raw material

Nature (e.g. hides and skin):

Animal species (e.g. bovine, pig):

Net weight (kg):

Identification mark (pallet or container):

2. Origin of the raw material

— *Slaughterhouse*

Address of the establishment:

.....

Veterinary approval/registration number:

— *Cutting plant*

Address of the establishment:

.....

Veterinary approval/registration number:

— *Meat products plant*

Address of the establishment:

.....

Veterinary approval/registration number:

— *Other animal products plant*

Address of the establishment:

.....

Registration number:

— *Wild game processing plant*

Address of the establishment:

.....

Veterinary approval number:

— *Fish products plant*

Address of the establishment:

.....

Veterinary approval/registration number:

— Collection centres

Address of the establishment:.....
.....

Registration number:
.....

— Tannery

Address of the establishment:.....
.....

Registration number:

— Retail shop

Address:.....
.....

— Premises adjacent to sales points, where the cutting and the storage of meat and poultry is performed for the sole purpose of supplying the final consumer directly

Address:.....

3. Destination of the raw material

Name of the collection centre/tannery/collagen plant ⁽¹⁾ where the raw material is sent:
.....

Address:.....
.....

4. Declaration

I, the undersigned, declare that I have read and understood the provisions of Parts III and IV of Section B of Chapter 4 of Annex II to Directive 92/118/EEC, and that:

- hides and skins from farmed ruminant animals/pig skins, bones and intestines/poultry skin and bones/tendons described above are derived from animals that have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following *ante* and *post mortem* inspections, and/or ⁽¹⁾
- hides and skins from wild game described above are derived from killed animals whose carcasses have been found fit for human consumption following the inspection laid down in Article 3 of Council Directive 92/45/EEC (OJ L 268, 24.9.1991, p. 15), and/or ⁽¹⁾
- fish skin and bones described above come from plants manufacturing fishery products for human consumption or registered in accordance with Council Directive 91/493/EEC (OJ L 268, 24.9.1991, p. 15) ⁽¹⁾.

Done at on.....
(place) (date)

.....
(Signature of the owner of the plant or his/her representative) ⁽²⁾

.....
(Name in block letters)

⁽¹⁾ Delete as appropriate.

⁽²⁾ The signature must be of a colour different from that of printing.

X(a) Health Certificate Model

for collagen intended for dispatch to the European Community for human consumption

Note for the importer: this certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection post.

Reference number of the health certificate:

Country of destination:

Exporting country:

Responsible Ministry:

Certifying department:

1. Identification of collagen

Type of products:

Animal species and nature of the raw materials used (e.g. bovine hides and skin):

.....

Date of manufacture:

Type of packaging:

Number of packages:

Guaranteed storage period:

Net weight (kg):

Address(es) and registration number(s) of authorised and registered production establishment(s):

.....

2. Destination of collagen

The collagen will be sent from:
(place of loading)

to:
(country and place of destination)

by the following means of transport ⁽¹⁾:

Name and address of consigner:

.....

Name and address of consignee:

.....

⁽¹⁾ Indicate the name or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship). This information is to be updated in the case of unloading and reloading.

3. Health attestation

I, the undersigned, declare that I am aware of the provisions of Section B of Chapter 4 of Annex II to Directive 92/118/EEC, and certify that the collagen described above:

- comes from establishments meeting the conditions laid down in Part II of that Section;
- has been produced from raw materials which met the conditions in Parts III and IV of that Section;
- has been produced in compliance with the conditions in Part V of that Section; and
- satisfies the conditions in Parts VI and VII(1) of that Section.

Done at on
(place) (date)

.....
(Signature of official veterinarian^(?))

.....
(Name in block letters)



^(?) The signature and the stamp must be of a colour different from that of printing.

X(b) Health Certificate Model

for raw material intended for dispatch to the European Community for the production of collagen for human consumption

Note for the importer: this certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection post.

Reference number of the health certificate:

Country of destination:

Exporting country:

Responsible Ministry:

Certifying department:

1. Identification of the raw material

Animal species and nature (e.g. bovine skin and hides, pig skin):

Date of production:

Type of packaging:

Number of packages:

Guaranteed storage period:

Net weight (kg):

2. Origin of raw material

Address(es) and registration number(s) of authorised and registered production establishment(s):

.....

3. Destination of raw material

The raw material will be sent from:

(place of loading)

to:

(country and place of destination)

by the following means of transport ⁽¹⁾:

Name and address of consigner:

.....

Name and address of consignee:

.....

⁽¹⁾ Indicate the name or registration number(railway wagons and lorries), the flight number (aircraft) or the name (chip). This information is to be updated in the case of unloading and reloading.

3. **Health attestation**

I, the undersigned, declare that I am aware of the provisions of Section B of Chapter 4 of Annex II to Directive 92/118/EEC, and certify that the raw material described above complies with the requirements of Part III of that Section and, in particular that:

- hides and skins of farmed ruminant animals/pig skins, bones and intestines/poultry skin and bones/tendons described above derive from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following *ante* and *post mortem* inspections; and/or ⁽²⁾
- wild game hides and skins described above derive from killed animals whose carcasses have been found fit for human consumption following the inspections laid down in Article 3 of Council Directive 92/45/EEC, and/or ⁽²⁾
- fish skin and bones described above derive from plants manufacturing fish products for human consumption authorised for export ⁽²⁾.

Done at on
(place) (date)

.....
(Signature of official veterinarian ⁽³⁾)

.....
(Name in block letters)



⁽²⁾ Delete as appropriate.

⁽³⁾ The signature and the stamp must be of a colour different from that of printing.

ANNEX III

I

CONSOLIDATED VERSION OF ANNEXES A AND B TO DIRECTIVE 89/662/EEC

ANNEX A VETERINARY LEGISLATION

CHAPTER I

- Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat (OJ No L 121, 29. 7. 1964, p. 2012/64).
- Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat (OJ No L 55, 8. 3. 1971, p. 23).
- Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat (OJ No L 302, 31. 12. 1972, p. 24).
- Council Directive 77/99/EEC of 21 December 1976 on health problems affecting intra-Community trade in meat products (OJ No L 26, 31. 1. 1977, p. 85).
- Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products (OJ No L 47, 21. 2. 1980, p. 4).
- Council Directive 88/657/EEC of 14 December 1988 laying down the requirements for the production of, and trade in, minced meat, meat in pieces of less than 100 grams and meat preparations (OJ No L 382, 31. 12. 1988, p. 3).
- Council Directive 89/437/EEC of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products (OJ No L 212, 22. 7. 1989, p. 87).
- Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1).
- Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs (OJ No L 268, 24. 9. 1991, p. 1).
- Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products (OJ No L 268, 24. 9. 1991, p. 15).
- Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat (OJ No L 268, 24. 9. 1991, p. 35).
- Council Directive 91/495/EEC of 27 November 1991 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat (OJ No L 268, 24. 9. 1991, p. 41).
- Council Directive 92/45/EEC of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat (OJ No L 268, 14. 9. 1992, p. 35).
- 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 (OJ No L 268, 14. 9. 1992, p. 1).

CHAPTER II

Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (with the exception of pathogens).

ANNEX B

PRODUCTS NOT SUBJECT TO COMMUNITY HARMONIZATION, BUT TRADE IN WHICH WOULD BE SUBJECT TO THE CHECKS PROVIDED FOR BY THIS DIRECTIVE

Other products of animal origin included neither in Annex B to this Directive nor in the Annex to Directive 90/425/EEC: these products will be defined under the procedure laid down in Article 18.

II

CONSOLIDATED VERSION OF ANNEXES A AND B TO DIRECTIVE 90/425/EEC

ANNEX A

CHAPTER I

VETERINARY LEGISLATION

Section 1

- Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ No 121, 29. 7. 1964, p. 1977/64).
- Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species (OJ No L 194, 22. 7. 1988, p. 10).
- Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (OJ No L 302, 19. 10. 1989, p. 1).
- Council Directive 90/426/EEC of 26 June 1990 on the health policy conditions governing the movement of equidae and their import from third countries (OJ No L 224, 18. 8. 1990, p. 42).
- Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (OJ No L 224, 18. 8. 1990, p. 62).
- Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs (OJ No L 303, 31. 10. 1990, p. 6).
- Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Directive 90/425/EEC (OJ No L 363, 27. 12. 1990, p. 51).
- Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1).
- Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ No L 46, 19. 2. 1991, p. 19).
- Council Directive 91/628/EEC of 19 November 1991 on the protection of animals during transport and amending Directives 90/425/EEC and 91/496/EEC (OJ No L 340, 11. 12. 1991, p. 17).

Section 2

Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) (1) to Directive 90/425/EEC (OJ No L 268, 14. 9. 1992, p. 54).

- For pathogens:

Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.

CHAPTER II

ZOOTECHNICAL LEGISLATION

- Council Directive 77/504/EEC of 25 July 1977 on pure-bred breeding animals of the bovine species (OJ No L 206, 12. 8. 1977, p. 8).
- Council Directive 88/661/EEC of 19 December 1988 on the zootechnical standards applicable to breeding animals of the porcine species (OJ No L 382, 31. 12. 1988, p. 36).
- Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats (OJ No L 153, 8. 6. 1989, p. 30).
- Council Directive 90/427/EEC of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae (OJ No L 224, 18. 8. 1990, p. 55).
- Council Directive 91/174/EEC of 25 March 1991 laying down zootechnical and pedigree requirements for the marketing of pure-bred animals (OJ No L 85, 5. 4. 1991, p. 37).

ANNEX B

ANIMALS AND PRODUCTS NOT SUBJECT TO HARMONIZATION BUT TRADE IN WHICH WILL BE SUBJECT TO THE CHECKS PROVIDED FOR IN THIS DIRECTIVE

CHAPTER I

Veterinary legislation - other live animals not listed in Annex A, Chapter I.

CHAPTER II

Veterinary legislation - semen, ova and embryos not listed in Annex A, Chapter I.'