COMMISSION REGULATION (EC) No 1234/2003

of 10 July 2003

amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 (TSEs) (1), as last amended by Commission Regulation (EC) No 1139/ 2003 (2), and in particular Article 23 thereof,

Whereas:

- Article 7 of Regulation (EC) No 999/2001 lays down (1)certain prohibitions concerning animal feeding. By way of a transitional measure, Commission Regulation (EC) No 1326/2001 (3), as amended by Regulation (EC) No 270/2002 (4), provides that Article 7 of Regulation (EC) No 999/2001 is not to apply to a Member State until the coming into force of the decision determining the bovine spongiform encephalopathy (BSE) status of that Member State, and until the Community provisions on animal feeding relevant to TSEs are effectively enforced in the Member State.
- Council Decision 2000/766/EC of 4 December 2000 (2) concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein (5), as last amended by Commission Decision 2002/248/EC (6), provides for the prohibition of feeding of processed animal protein to farmed animals which are kept fattened or bred for the production of food. However, under certain conditions, that prohibition does not apply to a number of processed animal proteins such as fishmeal, hydrolysed proteins and dicalcium phosphate, the use of which does not present a risk of TSEs nor hampers controls of proteins potentially posing a risk of TSEs.
- (3) Accordingly, Commission Decision 2001/9/EC of 29 December 2000 concerning control measures required for the implementation of Council Decision 2000/766/ EC concerning certain protection measures with regard

to transmissible spongiform encephalopathies and the feeding of animal protein (7), as last amended by Decision 2002/248/EC, established the conditions for the use of processed animal protein in feed not covered by the prohibition provided for in Decision 2000/766/EC.

- 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 (8), as amended by Commission Regulation (EC) No 808/2003 (9), lays down animal and public health rules for the collection, transport, storage, handling, processing and use or disposal of animal byproducts, including conditions for their use in animal feeding. That Regulation became applicable on 1 May 2003.
- Taking into account the fact that it is possible, although difficult, to differentiate between fishmeal and other processed animal proteins potentially posing a risk of TSEs, and also that Regulation (EC) No 1774/2002 introduced new provisions on the controls of all processed animal proteins, the conditions on the use of fishmeal as currently set out in Decision 2001/9/EC, should be simplified.
- The Scientific Steering Committee (SSC) indicated in its opinion of 17 September 1999 on intra-species recycling, and again in its opinion of of 27 and 28 November 2000 on the scientific basis for banning animal protein from feed for all farmed animals, that there is no evidence of the natural occurrence of TSE in non-ruminant farmed animals producing food, such as pigs and poultry.
- Animal proteins from such non-ruminant farmed animals are presently prohibited or restricted under Decisions 2000/766/EC and 2001/9/EC because they cannot be differentiated from prohibited ruminant proteins by current tests. However, certain proteins do not jeopardise the control of potentially infective processed animal protein in feedingstuffs and their use in animal feeding should therefore be authorised.

⁽¹) OJ L 147, 31.5.2001, p. 1. (²) OJ L 160, 28.6.2003, p. 22. (³) OJ L 177, 30.6.2001, p. 60. (⁴) OJ L 45, 15.2.2002, p. 4.

^{(&}lt;sup>5</sup>) OJ L 306, 7.12.2000, p. 32.

⁽⁶⁾ OJ L 84, 28.3.2002, p. 71.

^(*) OJ L 2, 5.1.2001, p. 32. (*) OJ L 273, 10.10.2002, p. 1. (*) OJ L 117, 13.5.2003, p. 1.

- (8) On 6 and 7 March 2003, the SSC adopted an opinion and report on the safety of dicalcium phosphate and tricalcium phosphate from bovine bones, used as animal feed or as fertiliser. Since tricalcium phosphate is not considered to present a TSE risk provided that certain processing conditions are complied with, and since it does not jeopardise the control of potentially infective animal protein, the use of tricalcium phosphate should be authorised.
- (9) As no decision has yet been taken concerning the determination of the BSE-status of Member States, and in the interests of clarity, the provisions set out in Decision 2000/766/EC should apply to all Member States regardless of their future BSE status. In addition, those provisions should be updated to take account of Regulation (EC) No 1774/2002.
- (10) In order to ensure that BSE is not transmitted to third countries through potentially contaminated processed animal protein, and to prevent the risk of their fraudulent re-introduction in the Community, the export of processed animal protein of ruminant origin, except when used in petfood, should be prohibited.
- (11) As and when the necessary control tools and reasonable evidence that the implementation of the current provisions is satisfactory in all Member States become available, the prohibition on the use of fishmeal to ruminants, the use of avian protein to farmed animals other than ruminants and the use of porcine protein to farmed animals other than ruminants should be reviewed.

- (12) Regulation (EC) No 999/2001 should therefore be amended accordingly. In addition, Decisions 2000/766/EC and 2001/9/EC should be repealed.
- (13) 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:

Article 1

Annexes I, IV and XI to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

Article 2

In Article 1 of Regulation (EC) No 1326/2001, point 2 is deleted.

Article 3

Decisions 2000/766/EC and 2001/9/EC are repealed. References to the repealed Decisions shall be construed as references to this Regulation.

Article 4

This Regulation shall enter into force on 1 September 2003.

The provisions of this Regulation shall be reviewed in the light of emerging scientific evidence and new control methods.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 July 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Annexes I, IV and XI to Regulation (EC) No 999/2001 are amended as follows:

1. Annex I is replaced by the following:

'ANNEX I

SPECIFIC DEFINITIONS

- For the purpose of this Regulation, the following definitions set out in Regulation (EC) No 1774/2002 of the European Parliament and of the Council (*), Regulation (EC) No 178/2002 of the European Parliament and of the Council (**) and Council Directive 79/373/EEC (***) shall apply:
 - (a) Regulation (EC) No 1774/2002:
 - (i) "farmed animal" in Article 2(1)(f);
 - (ii) "petfood" in point 41 of Annex I;
 - (iii) "processed animal protein" in point 42 of Annex I;
 - (iv) "gelatine" in point 26 of Annex I;
 - (v) "blood products" in point 4 of Annex I;
 - (vi) "bloodmeal" in point 6 of Annex I; and
 - (vii) "fishmeal" in point 24 of Annex I.
 - (b) the definition of "feedingstuff" in Article 3(4) of Regulation (EC) No 178/2002;
 - (c) the definition of "complete feedingstuff" in Article 2(d) of Directive 79/373/EEC.
- 2. For the purpose of this Regulation, the following definitions shall also apply:
 - (a) "indigenous case of BSE": means a case of bovine spongiform encephalopathy which has not been clearly demonstrated to be due to infection prior to importation as a live animal;
 - (b) "discrete adipose tissue": means internal and external body fat removed during the slaughter and cutting process, in particular fresh fat from the heart, caul and kidney of bovine animals, and fat from cutting rooms;
 - (c) "cohort": means a group of bovine animals which were,
 - (i) born in the same herd as the affected bovine animal, and within 12 months preceding or following the birth of the affected animal; or
 - (ii) reared together with the affected bovine animal at any time during the first year of their life and which may have consumed the same feed as that which the affected bovine animal consumed during the first year of its life.

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(*) OJ L 273, 10.10.2002, p. 1.
(**) OJ L 31, 1.2.2002, p. 1.
(***) OJ L 86, 6.4.1979, p. 30.'
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2. Annex IV is replaced by the following:

'ANNEX IV

ANIMAL FEEDING

Extension of the prohibition provided for in Article 7(1)

- 1. The prohibition provided for in Article 7(1) shall be extended to the feeding:
 - (a) to farmed animals, with the exception of the feeding of carnivorous fur producing animals, of:
 - (a) processed animal protein;
 - (b) gelatine of ruminant origin;
 - (c) blood products;
 - (d) hydrolysed protein;
 - (e) dicalcium phosphate and tricalcium phosphate of animal origin;
 - (f) feedingstuffs containing the proteins listed in points (a) to (e);
 - (b) to ruminants of animal protein and feedingstuffs containing such protein.

- 2. I. Derogations from the prohibitions provided for in Article 7(1) and (2), and specific conditions for the application of such derogations.
 - A. The prohibitions provided for in Article 7(1) and (2) shall not apply to:
 - (a) the feeding to non-ruminants of the proteins referred to in (i), (ii) and (iii), and of feedingstuffs derived from such proteins, provided that those proteins have been processed where applicable in accordance with Article 19 of Regulation (EC) No 1774/2002:
 - (i) fishmeal, in accordance with the conditions laid down in point B;
 - (ii) hydrolysed proteins derived from non-ruminants and ruminant hides and skins, in accordance with the conditions laid down in point C;
 - (iii) dicalcium phosphate and tricalcium phosphate, in accordance with the conditions laid down in point D;
 - (b) the feeding to ruminants of the proteins referred to in (i), (ii) and (iii), and of products derived from such proteins, provided that the proteins have been processed where applicable in accordance with the provisions in Article 19 of Regulation (EC) No 1774/2002:
 - (i) milk, milk-based products and colostrum;
 - (ii) eggs and egg products;
 - (iii) gelatine derived from non-ruminants;
 - (c) the feeding to fish of blood products and bloodmeal derived from non-ruminants, provided that they have been processed where applicable in accordance with Article 19 of Regulation (EC) No 1774/ 2002 and of feedingstuffs derived from such proteins, in accordance with the conditions laid down in point E.
 - B. Conditions for the use of fishmeal and feedingstuffs containing fishmeal in the feeding of non-ruminant farmed animals with the exception of carnivorous fur producing animals.
 - (a) The fishmeal shall be produced in processing plants dedicated exclusively to the production of fish derived products, which shall be approved for this purpose by the competent authority in accordance with Article 17 of Regulation (EC) No 1774/2002.
 - (b) Before release for free circulation in the Community, each consignment of imported fishmeal shall be analysed in accordance with Commission Directive 98/88/EC (*).
 - (c) Feedingstuffs containing fishmeal shall be produced in establishments which do not produce feedingstuffs for ruminants and which are authorised for this purpose by the competent authority.

However, by way of derogation from that condition:

- (i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing fishmeal is not required for home compounders:
 - registered by the competent authority,
 - keeping only non-ruminants,
 - producing complete feedingstuffs for use only in the same holding, and
 - provided that the feeding stuffs containing fishmeal used in the production contain less than $50\,\%$ crude protein;
- (ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing fishmeal for other animal species may be authorised by the competent authority subject to the following conditions:
 - bulk and packaged feedingstuffs destined for ruminants are manufactured in facilities physically separate from facilities where feedingstuffs containing fishmeal are manufactured,
 - bulk feedingstuffs destined for ruminants are kept in facilities physically separate from facilities where bulk fishmeal and bulk feedingstuffs containing fishmeal are kept during storage, transport and packaging,
 - records detailing the purchases and uses of fishmeal and the sales of feedingstuffs containing fishmeal are kept available to the competent authority for at least five years, and
 - routine tests are carried out on feedingstuffs destined to ruminants to ensure that prohibited proteins including fishmeal are not present.
- (d) The label and accompanying document of feedingstuffs containing fishmeal shall clearly indicate the words "contains fishmeal cannot be fed to ruminants".

- (e) Bulk feedingstuffs containing fishmeal shall be transported by means of vehicles which do not transport at the same time feedingstuffs for ruminants. If the vehicle is subsequently used for the transport of feedingstuffs intended for ruminants, it shall be thoroughly cleaned in accordance with a procedure approved by the competent authority to avoid cross-contamination.
- (f) The use and storage of feedingstuffs containing fishmeal shall be prohibited in farms where ruminants are kept.
 - By way of derogation from that condition, the competent authority may permit the use and storage of feedingstuffs containing fishmeal in farms where ruminants are kept, if they are satisfied that onfarm measures are implemented to prevent that feedingstuffs containing fishmeal are fed to ruminants
- C. Conditions for the use of hydrolysed proteins derived from non-ruminants or from ruminant hides and skins, and feedingstuffs containing such proteins, in the feeding of non-ruminant farmed animals, with the exception of the feeding of carnivorous fur producing animals.
 - (a) The hydrolysed proteins shall be produced in a processing plant approved by the competent authority in accordance with Article 17 of Regulation (EC) No 1774/2002.
 - (b) Feedingstuffs containing hydrolysed proteins shall be produced in establishments which do not prepare feedingstuffs for ruminants and which are authorised for this purpose by the competent authority.

However, by way of derogation from that condition:

- (i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing hydrolysed proteins is not required for home compounders:
 - registered by the competent authority,
 - keeping only non-ruminants,
 - producing complete feedingstuffs for use only in the same holding, and
 - provided that the feedingstuffs containing hydrolysed proteins used in the production contain less than 50 % crude protein;
- (ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing hydrolysed proteins for other animal species may be authorised by the competent authority subject to the following conditions:
 - bulk and packaged feedingstuffs destined for ruminants are manufactured in facilities physically separate from facilities where feedingstuffs containing hydrolysed proteins are manufactured.
 - bulk feedingstuffs destined for ruminants are kept in facilities physically separate from facilities
 where bulk hydrolysed proteins and bulk feedingstuffs containing hydrolysed proteins are kept
 during storage, transport and packaging,
 - records detailing the purchases and uses of hydrolysed proteins, and the sales of feedingstuffs
 containing hydrolysed proteins are kept available to the competent authority for at least five
 years.
- (c) The label and the accompanying document of the feedingstuffs containing hydrolysed proteins shall clearly indicate the words "contains hydrolysed proteins cannot be fed to ruminants".
- (d) Bulk feedingstuffs containing hydrolysed proteins shall be transported by mean of vehicles which do not transport at the same time feedingstuffs for ruminants. If the vehicle is subsequently used for the transport of feedingstuffs intended for ruminants, it shall be thoroughly cleaned in accordance with a procedure approved by the competent authority to avoid cross-contamination.
- (e) The use and storage of feedingstuffs containing hydrolysed proteins shall be prohibited in farms where ruminants are kept.
 - By way of derogation from that condition, the competent authority may permit the use and storage of feedingstuffs containing hydrolysed proteins in farms where ruminants are kept, if they are satisfied that on-farm measures are implemented to prevent the feeding of feedingstuffs containing hydrolysed proteins to ruminants.
- D. Conditions for the use of dicalcium phosphate, tricalcium phosphate and feedingstuffs containing such proteins in the feeding of non-ruminant farmed animals with the exception of the feeding of carnivorous fur producing animals.
 - (a) Dicalcium phosphate and tricalcium phosphate shall be produced in a processing plant approved by the competent authority in accordance with Article 17 of Regulation (EC) No 1774/2002.

(b) Feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall be produced in establishments which do not prepare feedingstuffs for ruminants and which are authorised for this purpose by the competent authority.

However, by way of derogation from that condition:

- (i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing dicalcium phosphate or tricalcium phosphate is not required for home compounders:
 - registered by the competent authority,
 - keeping only non-ruminants,
 - producing complete feedingstuffs for use only in the same holding, and
 - provided that the feedingstuffs containing dicalcium phosphate or tricalcium phosphate used in the production contain less than 10 % total phosphorus;
- (ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing dicalcium phosphate or tricalcium phosphate for other animal species may be authorised by the competent authority subject to the following conditions:
 - bulk and packaged feedingstuffs destined for ruminants are manufactured in facilities physically separate from facilities where feedingstuffs containing dicalcium phosphate or tricalcium phosphate are manufactured,
 - bulk feedingstuffs destined for ruminants are kept in facilities physically separate from facilities
 where bulk dicalcium phosphate and bulk tricalcium phosphate and bulk feedingstuffs
 containing dicalcium phosphate and tricalcium phosphate are kept during storage, transport
 and packaging,
 - records detailing the purchases and uses of dicalcium phosphate or tricalcium phosphate and the sales of feedingstuff containing dicalcium phosphate or tricalcium phosphate are kept available to the competent authority for at least five years.
- (c) The label and accompanying document of the feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall clearly indicate the words "contains dicalcium/tricalcium phosphate of animal origin — cannot be fed to ruminants".
- (d) Bulk feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall be transported by mean of vehicles which do not transport at the same time feedingstuffs for ruminants. If the vehicle is subsequently used for the transport of feedingstuffs intended for ruminants, it shall be thoroughly cleaned in accordance with a procedure approved by the competent authority to avoid cross-contamination.
- (e) The use and storage of feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall be prohibited in farms where ruminants are kept.
 - By way of derogation from that condition, the competent authority may permit the use and storage of feedingstuffs containing dicalcium phosphate or tricalcium phosphate in farms where ruminants are kept, if they are satisfied that on-farm measures are implemented to prevent that feedingstuffs containing dicalcium phosphate or tricalcium phosphate are fed to ruminants.
- E. Conditions for the use of blood products, bloodmeal and feedingstuffs containing such proteins of non-ruminant origin in the feeding of farmed fish:
 - (a) the blood shall be derived from EU approved slaughterhouses not slaughtering ruminants which are registered as not slaughtering ruminants and shall be transported directly to the processing plant in vehicles dedicated exclusively to the transport of non-ruminant blood. If the vehicle was used for the transport of ruminant blood, it shall be, following cleaning, inspected by the competent authority before the transport of non-ruminant blood.

By way of derogation from that condition, the competent authority may permit the slaughter of ruminants in slaughterhouses collecting non-ruminant blood intended for the production of blood meal and blood products for use in fish feed if these slaughterhouses have a recognised control system. The control system shall at least include:

- the slaughtering of non-ruminants physically separate from the slaughtering of ruminants,
- collection, storage, transport and packaging of blood from non-ruminant origin in facilities physically separate from facilities where blood of ruminant origin is collected, stored, transported and packaged, and
- regular sampling and analysis of blood from non-ruminant origin for the presence of ruminant proteins;

(b) the blood products and the bloodmeal shall be produced in an establishment exclusively processing non-ruminant blood and approved by the competent authority in accordance with Article 17 of Regulation (EC) No 1774/2002.

By way of derogation from that condition, the competent authority may permit the production of blood products for use in fish feed in establishments processing ruminant blood, which have a recognised control system in place preventing cross-contamination. The control system shall at least include:

- processing of non-ruminant blood in a closed system physically separate from the processing of ruminant blood,
- transport, storage and packaging of bulk raw material and bulk finished blood products of non-ruminant origin in facilities physically separate from facilities where bulk raw material and bulk finished products of ruminant origin are kept during storage, transport and packaging, and
- regular sampling and analysis of non-ruminant blood products for the presence of ruminant proteins;
- (c) feedingstuffs containing blood products or bloodmeal shall be produced in establishments manufacturing fish feed which do not prepare feedingstuffs for other farmed animals, with the exception of carnivorous fur producing animals, and which are authorised for that purpose by the competent authority;
- (d) the label, accompanying commercial document or health certificate, as appropriate, of the feedingstuffs containing blood products or bloodmeal shall clearly indicate the words "contains blood products — shall only be fed to fish" or "contains bloodmeal — shall only be fed to fish", as appropriate;
- (e) transport vehicles used for the transport of bulk fish feed containing blood products or bloodmeal shall not be used for the transport of feedingstuffs for other farmed animals, with the exception of carnivorous fur producing animals, unless the transport vehicle, following cleaning, has been inspected by the competent authority;
- (f) the use and storage of fish feed containing blood products or bloodmeal shall be prohibited in farms where other farmed animals, with the exception of carnivorous fur producing animals, are kept.

3. II. General implementing conditions

- A. Member States shall make available to the other Member States and to the Commission an up-to-date list of EU approved slaughterhouses registered as not slaughtering ruminants and approved processing establishments producing hydrolysed proteins, dicalcium phosphate, tricalcium phosphate, fishmeal, blood products or bloodmeal and establishments, with the exception of home compounders, authorised for manufacturing feedingstuffs containing these proteins, which operate in accordance with the conditions laid down by this Regulation within 60 days from the date of entry into force of this Regulation. Any amendments to the list shall immediately be made available to the other Member States and to the Commission.
- B. (a) Bulk processed animal protein, with the exception of fishmeal, and bulk feedingstuffs containing such proteins, shall be stored and transported in dedicated facilities. The store or vehicle can only be used for other purposes, following cleaning, after having been inspected by the competent authority.
 - (b) Bulk fishmeal, bulk hydrolysed proteins referred to in point A(a)(ii) of part I, bulk dicalcium phosphate and bulk tricalcium phosphate referred to in point A(a)(iii) of part I, and bloodmeal and blood products referred to in point A(c) of part I shall be stored and transported in stores and vehicles dedicated to that purpose.
 - (c) By way of derogation from point (b):
 - (i) stores or vehicles may be used for the storage and transport of feedingstuffs containing the same protein:
 - (ii) stores or vehicles, following cleaning, may be used for other purposes after having been inspected by the competent authority; and
 - (iii) vehicles transporting fishmeal may be used for other purposes if the company has a control system in place, recognised by the competent authority, to prevent cross-contamination. The control system shall at least include:
 - records on material transported and cleaning of the vehicle, and
 - regular sampling and analysis of feedingstuffs transported for the presence of fishmeal.

The competent authority shall carry out frequent spot checks to verify the correct application of the control plan.

C. Feedingstuffs, including petfood, which contain processed animal proteins, other than fishmeal or blood-meal of non-ruminant origin, or blood products of ruminant origin shall not be manufactured in establishments which produce feedingstuffs for farmed animals, with the exception of carnivorous fur producing animals.

Petfood and feedingstuffs intended for carnivorous fur producing animals containing fishmeal, hydrolysed proteins referred to in point A(a)(ii) of part I, dicalcium phosphate and tricalcium phosphate referred to in point A(a)(iii) of part I, and bloodmeal and blood products referred to in point A(c) of part I shall be manufactured and transported in accordance with the provisions referred to in points B(c) and (e), C(b) and (d), D(b) and (d) and E(c) and (e), respectively of part I.

D. The export to third countries of processed animal proteins derived from ruminants, and of products containing such processed animal proteins, shall be prohibited.

The export of other processed animal proteins and blood products and products containing such proteins shall only be permitted subject to the following conditions:

- they are destined for uses not prohibited by Article 7,
- a written agreement with the third country is made prior to exportation, which includes an undertaking from the third country to respect the final use and not to re-export the processed animal protein, blood products and products containing such proteins for uses prohibited by Article 7.

Member States which allow such exportation shall inform the Commission and the other Member States of all terms and conditions as agreed with the third country concerned, for the effective implementation of this Regulation, in the context of the Standing Committee on the Food Chain and Animal Health.

The measures in this point shall not apply to fishmeal, provided it fulfils the conditions set out in point B, products containing such fishmeal, and petfood.

- E. The competent authority shall carry out documentary and physical checks including tests on feedingstuffs throughout the production and distribution chain in accordance with Council Directive 95/53/EC (**), to control compliance with its provisions and the provisions of this Regulation. Where any presence of prohibited animal protein is detected, Council Directive 95/53/EC shall apply.
- F. The provisions on the production and the use of processed animal protein of Regulation (EC) No 1774/2002 shall apply to the feedingstuffs covered by this Annex.

(*) OJ L 318, 27.11.1998, p. 45. (**) OJ L 265, 5.11.1995, p. 17.

3. In Annex XI, Part C is deleted.