JUDGMENT OF THE COURT (Third Chamber)
1 April 2004 *

In Case C-286/02,

REFERENCE to the Court under Article 234 EC by the Tribunale di Treviso (Italy) for a preliminary ruling in the proceedings pending before that court between

Bellio F.lli Srl

and

Prefettura di Treviso

on the interpretation of Council Decision 2000/766/EC of 4 December 2000 concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein (OJ 2000 L 306, p. 32) and Commission Decision 2001/9/EC of 29 December 2000 concerning control measures required for the implementation of Decision 2000/766 (OJ 2001 L 2, p. 32),

* Language of the case: Italian.

THE COURT (Third Chamber),

composed of: A. Rosas (Rapporteur), President of the Chamber, R. Schintgen and N. Colneric, Judges,

Advocate General: L.A. Geelhoed,
Registrar: L. Hewlett, Principal Administrator,

after considering the written observations submitted on behalf of:

— Bellio F.lli Srl, by F. Capelli and R. Bordignon, avvocati,

— the Italian Republic, by I.M. Braguglia, acting as Agent, and P. Palmieri and M. Fiorilli, avvocati dello Stato,

— Ireland, by D.J. O'Hagan, acting as Agent, and N. Butler BL,

— the Kingdom of Norway, by I. Høyland and A. Enersen, acting as Agents,

— the Commission of the European Communities, by C. Cattabriga and V. Di Bucci, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Bellio F.lli Srl, represented by F. Capelli, the Italian Republic, represented by P. Palmieri, Ireland, represented by D.C. Smyth BL, the Kingdom of Norway, represented by A. Enersen, and the Commission, represented by V. Di Bucci, at the hearing on 4 December 2003,

after hearing the Opinion of the Advocate General at the sitting on 29 January 2004,

gives the following

Judgment

1 By order of 26 June 2002, received at the Court on 5 August 2002, the Tribunale di Treviso (Treviso District Court) referred to the Court for a preliminary ruling under Article 234 EC several questions, in particular on the interpretation of Council Decision 2000/766/EC of 4 December 2000 concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein (OJ 2000 L 306, p. 32) and Commission Decision 2001/9/EC of 29 December 2000 concerning control measures required for the implementation of Decision 2000/766 (OJ 2001 L 2, p. 32).

2 Those questions were raised in proceedings between Bellio F.lli Srl ('Bellio Fratelli') and the Prefettura di Treviso concerning the confiscation of a consignment of fish flour imported from Norway.

The relevant legislation

The Agreement on the European Economic Area

3 Article 6 of the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3, 'the EEA Agreement') provides:

'Without prejudice to future developments of case-law, the provisions of this Agreement, in so far as they are identical in substance to corresponding rules of the Treaty establishing the European Economic Community and the Treaty establishing the European Coal and Steel Community and to acts adopted in application of these two Treaties, shall, in their implementation and application, be interpreted in conformity with the relevant rulings of the Court of Justice of the European Communities given prior to the date of signature of this Agreement.'

4 Article 13 of that agreement is identical in substance to Article 30 EC and provides as follows:

'The provisions of Articles 11 and 12 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public

morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between the Contracting Parties.'

Article 20 of the EEA Agreement provides:

'Provisions and arrangements that apply to fish and other marine products are set out in Protocol 9.'

Article 2(5) of Protocol 9 of the EEA Agreement on the trade in fish and other marine products provides:

'The Community shall apply no quantitative restrictions on imports or measures having equivalent effect on the products listed in Appendix 2. In this context the provisions of Article 13 of the Agreement shall apply.'

7 Table I of Appendix 2 to that protocol provides:

HS Heading No	Description of goods
...	...
2301	Flours, meals and pellets, of meat or meat offal, of fish or of crustaceans, molluscs or other aquatic invertebrates, unfit for human consumption; greaves:
...	...

Decision 2000/766

8 Decision 2000/766 was adopted on the basis of 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 (OJ 1990 L 224, p. 29), as most recently amended by Council Directive 92/118/EEC of 17 December 1992 (OJ 1993 L 62, p. 49, 'Directive 90/425'), and in particular Article 10(4) thereof, and Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ 1998 L 24, p. 9), and in particular Article 22 thereof.

9 Paragraphs 1 and 2 of the grounds for Decision 2000/766 state that 'Community rules for control of certain processed animal protein in ruminant feed entered into force in July 1994' but that 'cases of bovine spongiform encephalopathy (BSE)

have been recorded in animals born in 1995 and later years in certain Member States'.

10 Paragraph 3 of the grounds of that decision also points out that 'the Scientific Steering Committee adopted an opinion on 27 and 28 November 2000 in which it recommended that, where the risk of cross-contamination of cattle feed with feed intended for other animals and which contains animal proteins possibly contaminated by the BSE agent cannot be excluded, a temporary ban of animal proteins in animal feed should be considered.'

11 The first sentence of paragraph 6 of the grounds of Decision 2000/766 states as follows:

'In the light of the above, as a precautionary measure, it is appropriate to prohibit on a temporary basis the use of animal protein in animal feed, pending a total re-evaluation of the implementation of Community legislation in Member States.'

12 Article 2 of that decision provides:

'1. Member States shall prohibit the feeding of processed animal proteins to farmed animals which are kept, fattened or bred for the production of food.

2. The prohibition referred to in paragraph 1 shall not apply to the feeding of:

— fishmeal to animals other than ruminants, in accordance with control measures to be fixed in accordance with the procedure laid down in Article 17 of Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ 1989 L 395, p. 13, as most recently amended by Directive 92/118 "Directive 89/662"),

— ...'

13 Article 3(1) of Decision 2000/766 provides that, with the exception of the derogations laid down in Article 2(2) thereof, the Member States are to prohibit the placing on the market, the trade, the importation from third countries and the exportation to third countries of processed animal proteins intended for the feeding of farmed animals which are kept, fattened or bred for the production of food, and are to ensure that such proteins are withdrawn from the market, distribution channels and from on-farm storage. Article 3(2) of that decision states that the Community provisions applicable to the collection, transportation, processing, storage and disposal of animal waste.

Decision 2001/9

14 Decision 2001/9 was adopted on the basis of Directive 89/662, and in particular Article 9(4) thereof, Directive 90/425, and in particular Article 10(4) thereof, and Directive 97/78, and in particular Article 22 thereof.

15 Article 1(1) of that decision provides:

'Member States shall authorise the feeding of fishmeal to animals other than ruminants only in accordance with the conditions laid down in Annex I.'

16 Annex I to that decision provides:

'1. Fishmeal shall be produced in processing plants dedicated only to fishmeal production, which are approved for this purpose by the competent authority in accordance with Article 5(2) of Directive 90/667/EEC.

2. Before release for free circulation in Community territory, each consignment of imported fishmeal shall be analysed in accordance with Commission Directive 98/88/EC [of 13 November 1998 establishing guidelines for the microscopic identification and estimation of constituents of animal origin for the official control of feedingstuffs (OJ 1998 L 318, p. 45)].

3. Fishmeal shall be transported directly from the processing plants to the establishments manufacturing animal feed, by means of vehicles which at the same time do not transport other feed materials. If the vehicle is subsequently used for the transport of other products, it shall be thoroughly cleaned and inspected before and after the transport of fishmeal.

4. Fishmeal shall be transported directly from the border inspection post to the establishments manufacturing animal feed, in accordance with the conditions laid down in Article 8 of Directive 97/78/EC, by means of vehicles which at the same time do not transport other feed materials. If the vehicle is subsequently used for the transport of other products, it shall be thoroughly cleaned and inspected before and after the transport of fishmeal.

5. By way of derogation from points 3 and 4, intermediate storage of fishmeal may be allowed only if it is carried out in dedicated storage plants which are authorised for this purpose by the competent authority.

6. Feedingstuffs containing fishmeal can be produced only in establishments manufacturing animal feed which do not prepare feedingstuffs for ruminant animals and which are authorised for this purpose by the competent authority.

By way of derogation from this provision, the production of feedingstuffs for ruminant animals in establishments which also produce feedingstuffs containing fishmeal for other animal species may be permitted by the competent authority on condition that:

— the transport and storage of feed materials destined to ruminant animals [are] completely separate from feed material prohibited for feeding to ruminant animals, and

— the storage, transport, manufacturing and packaging facilities for the compound feedingstuffs destined to ruminant animals are completely separate, and

— records detailing the purchases and uses of fishmeal and the sales of feedingstuffs containing fishmeal are made available to the competent authority, and

— routine tests are carried out on feedingstuffs destined to ruminant animals to ensure that prohibited processed animal proteins as defined by Article 1 of Decision 2000/766/EC are not present.

7. The labelling of feedingstuffs containing fishmeal shall clearly indicate the words "it contains fishmeal — cannot be fed to ruminant animals".

8. Bulk feedingstuffs containing fishmeal shall be transported by means of vehicles which at the same time do not transport feed for ruminant animals. If the vehicle is subsequently used for the transport of other products, it shall be thoroughly cleaned and inspected before and after the transport of bulk feedingstuffs containing fishmeal.

...'

17 Directives 89/662 and 90/425 form part of the EEA Agreement, as is apparent from Annex I to that agreement, entitled 'Veterinary and phytosanitary matters', in the version arising from Decision of the EEA Joint Committee No 69/98 of 17 July 1998 (OJ 1999 L 158, p. 1). Decisions 2000/766 and 2001/9 were incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 65/2003 of 20 June 2003 amending Annex I (Veterinary and phytosanitary matters) to the EEA Agreement (OJ 2003 L 257, p. 1).

Directive 98/34/EC

18 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1998 L 204, p. 37) codified Council Directive 83/189/EEC of 28 March 1983 (OJ 1983 L 109, p. 8). It was amended by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 (OJ 1998 L 217, p. 18).

19 Articles 8 and 9 of Directive 83/189 require the Member States to communicate to the Commission of the European Communities any draft technical regulations which they intend to adopt and to postpone adoption thereof until the expiry of a certain period of time from the date upon which the Commission receives that communication.

20 The first indent of Article 10(1) of Directive 98/34 nevertheless provides that Articles 8 and 9 thereof shall not apply to those laws, regulations and administrative provisions of the Member States by means of which they comply with binding Community acts which result in the adoption inter alia of technical specifications.

Facts, procedure in the main proceedings and questions referred for a preliminary ruling

21 It is apparent from the order for reference that:

'— in January 2000, Bellio imported from Norway a consignment of fish flour, subsequently purchased by Mangimificio SAPAS Sas of San Miniato (PI), for the production of feedingstuffs for animals other than ruminants;

— from samples taken at the premises of SAPAS Sas during on-the-spot inspections carried out by competent officers of the Judicial Police of the Service for the Protection of Hygiene and Health, the fish flour was found to contain fragments of unidentified animal bones, with the result that the consignments of fish flour supplied by the applicant were seized;

— independent analysis carried out on behalf of Bellio found the fish flour to contain fragments of mammalian bone tissue amounting to less than 0.1%;

— the review of the analysis carried out by the Board of Health on 27 September 2001 confirmed the presence of bone fragments;

— on the basis of the fragments of mammalian bone tissue found, an administrative sanction was imposed on Bellio F.lli Srl pursuant to Article 17(a) and the first and third paragraphs of Article 22 of Law No 281 of 15

February 1963, as subsequently amended and supplemented, "for having sold a simple feedingstuff, namely fish flour, packaged and marketed in such a way as to mislead the purchaser as to the composition, type and nature of the product, and which appears from analysis not to conform to the representations, indications and descriptions on the label and in the contract documentation accompanying the product", in the form of an order for the confiscation and destruction of 36 sacks of the fish flour, as identified in Seizure Order No 17 of 21 February 2001, and an order to pay a fine of EUR 18 597.27, without prejudice to any other related and/or consequential order, whether interlocutory or final.'

22 On appeal by Bellio Fratelli, the Tribunale di Treviso held it to be necessary to refer to the Community rules governing the use of fish flour as a component of animal feedingstuffs in order to ascertain whether there had been any breach of those rules in this matter. Accordingly, it considered that Decisions 2000/766 and 2001/9 were relevant in the circumstances of the present case.

23 The Tribunale di Treviso nevertheless held that, given the percentage of mammalian bone fragments present in the fish flour, that presence might have been the result of accidental contamination. Consequently, the general principle, accepted in various domains of Community law, of reasonable tolerance applied. If this were not the case, there would be an obligation to comply with a technical standard which would have to have been authorised by the Commission, in accordance with Directive 83/189, as codified by Directive 98/34.

24 The Tribunale di Treviso stated that as the fish flour in question came from Norway, which forms part of the EEA, it was governed by the Community principles concerning the freedom of movement of goods, pursuant to Articles 8 to 16 of the EEA Agreement.

25 The Tribunale di Treviso decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling pursuant to Article 234 EC:

'1. Are the first indent of Article 2(2) of Decision [2000/766] and Article 1(1) of Decision [2001/9], read together with the other Community rules on which those provisions are based, to be interpreted as meaning that the accidental presence of an unforeseen or prohibited substance in fish flour used in the production of feedingstuffs for animals other than ruminants may be considered to be acceptable de jure or de facto and that, accordingly, traders are allowed a reasonable level of tolerance?

2. If so, in the light of the principle of proportionality and the precautionary principle, and in consideration of the Community provisions applicable in the domains in which reference is made to accidental contamination of food-industry products and indications are given of relevant levels of tolerance, does an accidental contamination of 0.1%, and in any case of not more than 0.5%, of fragments of mammalian bone in fish flour intended for the production of feedingstuffs for animals other than ruminants warrant the adoption of a drastic sanction such as the complete destruction of that fish flour?

3. Does the exclusion of any tolerance in relation to the presence of the substances mentioned in the preceding questions amount to the introduction of a technical standard within the meaning of Directive [83/189] which would have to have been notified in advance to the European Commission?

4. Are the provisions of Articles 28 and 30 EC on the free movement of goods, applicable to Norway on the basis of Articles 8 to 16 of the [EEA] Agreement, to be interpreted, with reference to the provisions contained in Decision 2000/766 and Decision 2001/9 cited in Question 1 above, as meaning that a Member State may not require zero tolerance in a situation such as that described in Questions 1 and 2 above?'

Admissibility of the questions referred for a preliminary ruling

26 The Italian Republic considers that the questions raised by the Tribunale di Treviso are manifestly not relevant for the purposes of resolving the dispute pending before that court. It points out that Article 17(a) of Law No 281 of 1963 penalises the distribution of goods 'which are not of sound, fair and merchantable quality, which are a danger to animal or human health and which are presented in a manner such as to mislead the purchaser'. In the case in the main proceedings, however, the infringement found concerns more the misrepresentation of the goods sold and presented in such a way as to mislead the purchaser than the marketing of goods which are harmful to health. The answer to the questions raised by the Tribunale di Treviso is not therefore a necessary precondition for the determination of the dispute in the main proceedings given that, even if the answer to the questions referred to the Court of Justice is in the affirmative, the legality of the sanctions adopted is also justified by the fact that potential purchasers were misled, or by Bellio Fratelli's misrepresentation of the products for sale.

27 It should be recalled in this connection that, according to settled case-law, it is solely for the national courts before which actions are brought, and which must bear the responsibility for the subsequent judicial decision, to determine in the light of the special features of each case both the need for a preliminary ruling in

order to enable them to deliver judgment and the relevance of the questions which they submit to the Court. Consequently, since the questions referred involve the interpretation of Community law, the Court is, in principle, obliged to give a ruling (see, inter alia, Case C-379/98 *PreussenElektra* [2001] ECR I-2099, paragraph 38; Case C-390/99 *Canal Satélite Digital* [2002] ECR I-607, paragraph 18; Case C-373/00 *Adolf Truley* [2003] ECR I-1931, paragraph 21, and Case C-18/01 *Korhonen and Others* [2003] ECR I-5321, paragraph 19).

28 Moreover, it also follows from that case-law that the Court may decline to rule on a question referred for a preliminary ruling by a national court only where it is quite obvious that the interpretation of Community law that is sought bears no relation to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (see *PreussenElektra*, cited above, paragraph 39; *Canal Satélite Digital*, cited above, paragraph 19; *Adolf Truley*, cited above, paragraph 22, and *Korhonen*, cited above, paragraph 20).

29 That is not so in the present case because it is not quite obvious that the questions referred for a preliminary ruling are not necessary for the national court, even if the infringement found was the misrepresentation of goods offered for sale and presented in a manner such as to mislead the purchaser. Furthermore, the Court has before it the factual and legal material necessary to give a useful answer to the questions referred to it.

30 Consequently, the questions referred for a preliminary ruling by the Tribunale di Treviso are admissible.

Applicable law

31 In the case of fish flour imported from Norway, Article 2(5) of Protocol 9 of the EEA Agreement, on the trade in fish and other marine products, is applicable since the Kingdom of Norway is a Contracting Party to that agreement. That article states that 'the Community shall apply no quantitative restrictions on imports or measures having equivalent effect' on such products unless those restrictions or measures are justified pursuant to Article 13 of the EEA Agreement. Under the latter article prohibitions or restrictions may be justified inter alia on grounds of the protection of health and life of humans and animals.

32 It is necessary in that context to ascertain whether the Community rules are justified on grounds of the protection of health and life of humans and animals within the meaning of Article 13 of the EEA Agreement or whether those rules constitute a measure having equivalent effect prohibited by Article 2(5) of Protocol 9 of that agreement.

33 It should be recalled that the EEA Agreement was concluded by the European Economic Community and the European Coal and Steel Community, referred to in that agreement as 'the Community'. Article 300(7) EC provides that 'agreements concluded under the conditions set out in this article shall be binding on the institutions of the Community and on Member States'. Furthermore, the Court has held that the primacy of international agreements concluded by the Community over provisions of secondary Community legislation means that such provisions must, so far as is possible, be interpreted in a manner that is consistent with those agreements (Case C-61/94 *Commission* v *Germany* [1996] ECR I-3989, paragraph 52).

34 It should be emphasised in this connection that, as Article 6 of the EEA Agreement states, the provisions of the agreement, in so far as they are identical in substance to corresponding rules of the EC Treaty and to acts adopted in application of that Treaty, must, in their implementation and application, be interpreted in conformity with the relevant rulings of the Court given prior to the date of signature of the EEA Agreement. Furthermore, both the Court and the EFTA Court have recognised the need to ensure that the rules of the EEA Agreement which are identical in substance to those of the Treaty are interpreted uniformly (Case C-452/01 *Ospelt and Schlössle Weissenberg Familienstiftung* [2003] ECR I-9743, paragraph 29, and Case E-1/03 *EFTA Surveillance Authority* v *Iceland*, not yet published in the EFTA Court Reports, paragraph 27).

35 As was noted at paragraph 4 of the present judgment, Article 13 of the EEA Agreement is identical in substance to Article 30 EC.

36 It is necessary to take account of these factors in order to give useful answers to the national court.

The questions referred for a preliminary ruling

The first, second and fourth questions

37 It is convenient to examine the first, second and fourth questions together. By those questions, the national court asks essentially whether the Community provisions relating to animal flour must be applied with 'zero tolerance' or

whether fish flour permitted under certain circumstances remains marketable even where it contains a tiny proportion of fragments of mammalian bone tissue, probably as a result of accidental contamination.

Observations submitted to the Court

38 Bellio Fratelli submits that the Community rules must be interpreted as meaning that a certain tolerance of accidental contamination should be acceptable. It refers in that connection to the rules on genetically modified organisms ('GMOs'), which provide for a level of tolerance of contamination of 1%, and more particularly to Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC (OJ 1998 L 159, p. 4), and to Commission Regulation (EC) No 49/2000 of 10 January 2000 amending Council Regulation (EC) No 1139/98 (OJ 2000 L 6, p. 13). Analysis of the fish flour is not capable of determining whether it constitutes a health risk since the mammalian fragments could come from animals not 'at risk', such as whale or rat. Moreover, this is a foodstuff intended for consumption not by humans as was so in Case C-121/00 *Hahn* [2002] ECR I-9193, but by pigs, which have never been shown to contract BSE. Bellio Fratelli concludes that the sanction imposed by the Prefettura di Treviso of destruction of the product is contrary to the Community rules and, in any event, disproportionate having regard to the objective of the protection of public health.

39 The Italian Republic, Ireland, the Kingdom of Norway and the Commission submit that, in so far as the Community rules apply even to the sanction, they do not permit any contamination, even accidental. They insist on the objective of public health which is the purpose of the ban on animal flours and, more particularly, on the objective of the prevention of cross-contamination, that is,

accidental contamination; the fact that authorisation of fish flour is an exception to the principle that animal flours are banned; that the provisions relating to the conditions of that authorisation must be interpreted restrictively and, finally, the absence of any implied 'principle of tolerance' in Community law. They point to the state of scientific knowledge in relation to BSE and the view of experts that exposure to a minimal quantity of infected product may cause disease. They draw attention to the fact that the presence of a tiny quantity of bone fragments, only observable through a microscope, does not indicate the quantity of mammalian soft tissue which may be present in the product. They conclude that the Community rules must be interpreted strictly and that the destruction of the product is justified and not disproportionate. In any event, the national rules imposing zero tolerance and providing for the destruction of the product comply with Article 30 EC and the corresponding provisions of the EEA Agreement. At the hearing, the Commission stated that the application of Decisions 2000/766 and 2001/9 is monitored and that those decisions have been regularly amended so as to take account of developments in scientific knowledge. They have been incorporated into the EEA Agreement, which demonstrates their validity.

Reply of the Court

40 In order to interpret Decisions 2000/766 and 2001/9, it is necessary to examine, apart from their wording and structure, their context and purpose. The latter may be inferred in particular from the legal bases on which those decisions were adopted and the paragraphs of the grounds of those decisions. Finally, it is necessary to take account of the relevant provisions of the Treaty.

41 The decisions in question were adopted to combat transmissible spongiform encephalopathies ('TSEs'). The commonly accepted working hypothesis amongst the scientific community is that these diseases, including the Creutzfeldt-Jakob variant which affects humans and has caused the death of many people, are

primarily transmitted orally, that is by the ingestion of food containing prions (see 'Opinion on hypotheses on the origin and the transmission of BSE adopted by the Scientific Steering Committee at its meeting of 29 and 30 November 2001'). Indeed it is the ban on the feeding of animal flours to ruminants which has produced most results in combating these diseases, although they have not disappeared completely.

42 In its opinion of 27 and 28 November 2000, cited in paragraph 3 of the grounds of Decision 2000/766, the Scientific Steering Committee referred to the risk of cross-contamination of cattle feed with feed intended for other animals and which contains animal proteins possibly contaminated by the BSE agent. It recommended the temporary ban of animal proteins in animal feed.

43 When asked about the quantity of infected material likely to trigger disease, the Scientific Steering Committee, after public consultation of the scientific community, acknowledged in the opinion adopted at its meeting on 13 and 14 April 2000 that it was impossible for it to identify precisely the minimum amount of infected material required to lead to disease in humans.

44 It is in the light of those factors, and of Article 152 EC, which provides that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities, that Decisions 2000/766 and 2001/9 should be interpreted.

45 Whilst it is true that those two decisions impose exceptions on the free movement of goods, in that they contain various prohibitions on animal proteins, it should be borne in mind that they were adopted on the basis of Directives 89/662 and 90/425 which, incorporated into Annex I to the EEA Agreement entitled

'Veterinary and phytosanitary matters', are intended precisely to ensure the free movement of agricultural products within the EEA (see, on the subject of free movement within the Community, Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 63).

46 Having regard to the public health objective pursued by those decisions, they must be interpreted widely and the exception they lay down in respect of fish flour must be interpreted narrowly.

47 Contrary to Bellio Fratelli's submission, it is not true that the decisions do not contain any provision concerning accidental contamination. Paragraph 3 of the grounds of Decision 2000/766 refers to the opinion of the Scientific Steering Committee of 27 and 28 November 2000 on the risk of cross-contamination of cattle feed. It appears from discussions before that committee that it defines cross-contamination as accidental contamination which may occur during the production of the raw material, transport, storage, production of feeds or their handling within farms with mixed breeding, that is, of ruminants and other animals (report and scientific opinion on mammalian-derived meat and bone meal forming a cross-contaminant of animal feedingstuffs adopted by the Scientific Steering Committee at its meeting of 24 and 25 September 1998, point 2 (Definitions)).

48 It is precisely so as to avoid such accidental contamination that Annex I to Decision 2001/9 contains particularly strict provisions relating to the total separation of the chains of production, transport and storage of raw materials, but also of the storage, transport, production and packaging of compound feedingstuffs, as fish flours are not permitted to come into contact with feed prepared for ruminants. That annex also contains provisions relating to the cleaning of vehicles and their inspection.

49 The fact that the fish flour was intended for pigs does not justify a different interpretation of Decisions 2000/766 and 2001/9. It should be noted that Article 2 (2) of Decision 2000/766 envisages just such a case since the use of fish flour is permitted only in respect of feedingstuffs for animals other than ruminants. As the Scientific Steering Committee stated, the cross-contamination of cattle likely to develop BSE can arise from any of the phases of handling of the product, even if the flour is in fact used to feed animals other than ruminants.

50 Similarly, the speculation that the mammalian bones come from mammals other than ruminants, such as whales or rats, is not sufficient to demonstrate that the Community measure is inappropriate or disproportionate having regard to the risks involved and the means of analysis of the products.

51 Furthermore, it matters little that the degree of contamination of the product is low. It should be borne in mind that, in accordance with point 2 of Annex I to Decision 2001/9, the consignments of fish flour are analysed in accordance with Directive 98/88. The microscopic examinations laid down by that directive enable the presence of mammalian matter, in particular bones, to be detected, but do not enable the quantity of soft tissue present in the product to be determined.

52 Furthermore, as was pointed out in paragraph 43 of the present judgment, the Scientific Steering Committee acknowledged that it was impossible for it to identify precisely the minimum quantity of infected material necessary to give rise to TSE in humans.

53 In this respect the argument derived from the rules on GMOs is neither relevant nor cogent. GMOs differ from TSEs, in that those diseases have caused the death of many people and necessitated the slaughter of thousands of animals.

Furthermore, the fact that the rules on GMOs expressly set a de minimis threshold of 1% for the accidental presence of GMOs does not support Bellio Fratelli's argument that all Community rules implicitly allow tolerance of accidental contamination of not more than 1%. The express mention of a reasonable level of tolerance for accidental contamination may be interpreted as meaning that the failure to set such a threshold implies that there is no tolerance of accidental contamination.

54 With regard to the destruction of the contaminated consignments, it should be noted that this is a measure provided for by Article 3(1) of Decision 2000/766. A contaminated consignment must be regarded as unfit for consumption and must if necessary be destroyed whilst taking all necessary precautions to avoid environmental contamination. It suffices in this connection to state that the risk of environmental contamination is one of the risks taken into account by the Scientific Steering Committee in the opinion of 27 and 28 November 2000 (see paragraph 3 thereof).

55 It follows that destruction cannot be regarded as a sanction, but is a preventive measure laid down by Community law which, in that respect, leaves no discretion to the Member States.

56 It follows from all these considerations that the answer to the questions referred must be that the first indent of Article 2(2) of Decision 2000/766 and Article 1(1) of Decision 2001/9, together with the other Community rules on which those provisions are based, must be interpreted as meaning that the presence, even accidental, of unauthorised substances in fish flour used in the production of feedingstuffs intended for animals other than ruminants is not permitted and that they allow traders no level of tolerance. The destruction of consignments of contaminated flour is a preventive measure provided for by Article 3(1) of Decision 2000/766.

57 With regard to the justification of those provisions in the light of Article 13 of the EEA Agreement, it should be noted that in the absence of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research, it is for the Contracting Parties to decide on the level of protection of human health they wish to ensure, taking account of the fundamental requirements of EEA law and, in particular, the free movement of goods in the EEA (Case E-3/00 *EFTA Surveillance Authority* v *Norway* [2000-2001] EFTA Court Report p. 73, paragraph 25; see, in this connection, with regard to the free movement of goods in the Community, Case 174/82 *Sandoz* [1983] ECR 2445, paragraph 16; Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 42, and Case C-24/00 *Commission* v *France* [2004] ECR I-1277, paragraph 49).

58 This means that a risk-management decision rests with each Contracting Party, which has a discretion as to the level of risk it considers appropriate. Under those conditions, those parties may invoke the precautionary principle, according to which it is sufficient to show that there is relevant scientific uncertainty with regard to the risk in question. That discretion must, however, be open to judicial review (*EFTA Surveillance Authority* v *Norway*, cited above, paragraph 25).

59 Measures taken by a Contracting Party must be based on scientific evidence; they must be proportionate, non-discriminatory, transparent, and consistent with similar measures already taken (*EFTA Surveillance Authority* v *Norway*, paragraph 26).

60 Thus, even if the need to safeguard public health has been recognised as a primary concern, the principle of proportionality must be respected (see, to that effect, *EFTA Surveillance Authority* v *Norway*, paragraph 27).

61 In the present case, the measures adopted form part of a coherent body of legislation the purpose of which is to combat TSEs. They were adopted on the recommendation of experts having at their disposal the relevant scientific data and they are applicable without distinction to all fish flour likely to be used in the Community. In the light of the matters set out in paragraphs 40 to 56 of the present judgment, those measures do not infringe the principle of proportionality of EEA law.

62 It follows that those measures are justified by the protection of human and animal health within the meaning of Article 13 of the EEA Agreement. That conclusion is supported by the fact that on 20 June 2003, Decisions 2000/766 and 2001/9 were incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 65/2003.

63 Accordingly, the answer to the questions referred must be that Article 13 of the EEA Agreement must be interpreted as meaning that Decisions 2000/766 and 2001/9 are not incompatible therewith.

The third question

64 It is apparent from the statement of reasons in the order for reference that the third question was asked only if the exclusion of any level of tolerance was considered to be a measure adopted by a Member State. As that is not the case, because that exclusion arises from the Community rules themselves, there is no need to reply to that question.

Costs

65 The costs incurred by the Irish, Italian and Norwegian Governments and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main action, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Third Chamber),

in answer to the questions referred to it by the Tribunale di Treviso by order of 26 June 2002, hereby rules:

1. **The first indent of Article 2(2) of Council Decision 2000/766/EC of 4 December 2000 concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein, and Article 1(1) of Commission Decision 2001/9/EC of 29 December 2000 concerning control measures required for the implementation of Decision**

2000/766, together with the other Community rules on which those provisions are based, must be interpreted as meaning that the presence, even accidental, of unauthorised substances in fish flour used in the production of feedingstuffs intended for animals other than ruminants is not permitted and that they allow traders no level of tolerance. The destruction of consignments of contaminated flour is a preventive measure provided for by Article 3(1) of Decision 2000/766.

2. Article 13 of the European Economic Area Agreement of 2 May 1992 must be interpreted as meaning that Decisions 2000/766 and 2001/9 are not incompatible therewith.

Rosas Schintgen Colneric

Delivered in open court in Luxembourg on 1 April 2004.

R. Grass

Registrar

A. Rosas

President of the Third Chamber