OPINION OF ADVOCATE GENERAL COSMAS
delivered on 10 December 1996 *

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I — Introduction

1. In connection with an application for interim measures, the College van Beroep voor het Bedrijfsleven (Administrative Court for Trade and Industry) has submitted to the Court for a preliminary ruling pursuant to Article 177 of the Treaty a question concerning the validity of Commission Decision 95/119/EC of 7 April 1995 concerning certain protective measures with regard to fishery products originating in Japan. [1]

2. This case concerns a review by the Court of the validity of measures for the protection of public health which the Commission adopts by virtue of its powers under Article 19 of Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries. [2]

3. At the same time, this case also gives the Court the opportunity to rule for the first time on the question whether the provisions of the Agreement on the application of sanitary and phytosanitary measures (hereinafter 'the Agreement'), [3] which forms part of

1 — OJ 1995 L 80, p. 56.

2 — OJ 1990 L 373, p. 1.

3 — OJ 1994 L 336, p. 40.

Annex 1A to the Agreement establishing the World Trade Organization (hereinafter 'the WTO'), [4] have direct effect.

II — The legal framework

A — *The Community provisions*

4. A series of Community provisions form the framework of substantive and procedural rules concerning veterinary checks on products imported into the Community, in particular fishery products.

(1) *Council Directive 91/493/EEC*

5. 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, [5] sets out, in Chapter II, which deals with imports from third countries, the veterinary conditions which fishery products entering the Community from third countries must fulfil and the checks and inspections which those products must undergo (Articles 10 to 12).

6. Article 10 sets forth the principle that the provisions governing the importation of fishery products from third countries must be at least equivalent to those governing the production and placing on the market of Community products. The provision is worded as follows:

'Provisions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of Community products.

...'.

7. In order to ensure that imported products satisfy the requirements laid down by the Community provisions, Article 11 provides for the possibility of fixing specific import conditions based on a system of approved establishments from which fishery products

4 — OJ 1994 L 336, p. 3.
5 — OJ 1991 L 268, p. 15.

may be exported to the Community. Article 11 is worded as follows:

'1. For each third country or group of third countries, fishery products must fulfil the specific import conditions ..., depending on the health situation in the third country concerned.

2. In order to allow the import conditions to be fixed, and in order to verify the conditions of production, storage and dispatch of fishery products for consignment to the Community, inspections may be carried out on the spot by experts from the Commission and the Member States.

...

3. When fixing the import conditions of fishery products referred to in paragraph 1, particular account shall be taken of:

(a) the legislation of the third country;

(b) the organization of the competent authority of the third country and of its inspection services, the powers of such services and the supervision to which they are subject, as well as their facilities for effectively verifying the implementation of their legislation in force;

(c) the actual health conditions during the production, storage and dispatch of fishery products intended for the Community;

(d) the assurances which a third country can give on the compliance with the standards laid down in Chapter V of the Annex.

4. The import conditions referred to in paragraph 1 shall include:

(a) the procedure for obtaining a health certificate which must accompany consignments when forwarded to the Community;

(b) the placing of a mark identifying the fishery products, in particular with the approval number of the establishment of origin, except in the case of frozen fishery products, landed immediately for canning and bearing the certificate provided for under (a);

(c) drawing up a list of approved establishments and auction or wholesale markets registered and approved by the Commission ... .

For that purpose, one or more lists of such establishments shall be drawn up on the basis of a communication from the competent authorities of the third country to the Commission. An establishment may not appear on a list unless it is officially approved by the competent authority of the third country exporting to the Community. Such approval shall be subject to observance of the following requirements:

— compliance with requirements equivalent to those laid down in this directive,

— monitoring by an official inspection service of the third country.

...'. [6]

8. Article 11(7) provides that, pending the fixing of the specific import conditions, the conditions applied to imports from third countries must be at least equivalent to those governing the production and placing on the market of Community products.

9. In Decision 93/185/EEC of 15 March 1993 laying down certain transitional measures concerning the certification of fishery products from third countries in order to facilitate the switchover to the arrangements laid down in Council Directive 91/493/EEC, [7] the Commission stipulated that fishery products imported into the Community from third countries, for which no specific import conditions have been fixed, must be accompanied by health certificates complying with the model set out in the Annex.

10. Article 3 of Decision 93/185 provided that the arrangements contained therein would apply from 1 July 1993 until 31 December 1994. The period of validity was extended until 1 March 1995 by Council Decision 94/941/EC of 14 December 1994. [8] Decision 94/941 maintained until that date (1 March 1995) the conditions which had applied until then to imports of fishery products, as referred to in Article 11(7) of

6 — Chapter V of the Annex, to which reference is made in paragraph 3(d), concerns the health control and monitoring of production conditions.

7 — OJ 1993 L 79, p. 80.

8 — OJ 1994 L 366, p. 34.

Directive 91/493. [9] The period of validity was subsequently extended until 30 June 1995 by Council Decision 95/49/EC [10] of 27 February 1995.

11. Article 12(1) of Directive 91/493 provides that the procedure and the inspections to be carried out by the Member States, as well as the safeguard provisions to be implemented, must be laid down on the basis of Directive 90/675/EEC, to which express reference is made.

(2) *Council Directive 90/675/EEC*

12. Council Directive 90/675/EEC of 10 December 1990 [11] lays down the principles governing the organization of veterinary checks on products entering the Community from third countries.

13. Chapter II contains specific 'safeguard provisions' intended to ensure efficient and timely protection of public health. Article 19 thereof is worded as follows:

'1. If, in the territory of a third country, a disease ..., a zoonosis or other disease or phenomenon liable to present a serious threat to animal or public health, or if any other serious animal health or public health reason so warrants in particular in the light of the findings of its veterinary experts, the Commission may, acting on its own initiative or at the request of a Member State, adopt one of the following measures without delay and depending on the gravity of the situation:

— suspend imports coming from part or all of the third country concerned, and where appropriate from the transit third country,

— set special conditions in respect of imports coming from part or all of the third country concerned.

...

4. Representatives of the Commission may make an immediate visit to the third country concerned.

...

9 — From 1 July 1995, Decision 93/185 was replaced by Commission Decision 95/328/EC of 27 July 1995 establishing health certification for fishery products from third countries which are not yet covered by a specific decision (OJ 1995 L 191, p. 32). The period of validity of that decision was fixed as two years. Article 1(1) of the decision provides that consignments of fishery products introduced into the Community must (a) come from an agreed establishment inspected by the competent authority of the third country and (b) be accompanied by a numbered original health certificate attesting that the health conditions of production, handling, processing, packaging and identification of the products are at least equivalent to those established by Directive 91/493. The model of the health certificate is laid down in the Annex.

10 — OJ 1995 L 53, p. 30.

11 — Directive already cited in footnote 2.

6. Without delay the Commission shall review the situation within the Standing Veterinary Committee. ...'

(3) *Commission Decision 95/119/EC*

14. Between 27 and 31 March 1995, experts from the Commission conducted an investigation in Japan of the conditions of production and processing of fishery products which were to be exported to the Community. Four establishments, which were chosen by the competent Japanese authorities, as well as the fish market in Tokyo, were visited. [12]

12 — In its written observations (point 10), the Commission points out that, with regard to Japan, the specific conditions referred to in Article 11(1) of Directive 91/493 for imports of fishery products have not yet been fixed. On 22 March 1995, the Japanese authorities sent to the Commission a list of 80 approved establishments. Once the Commission's inspections, provided for by Article 11(2) of Directive 91/493, of the control system operated by those authorities had been carried out and that system had been approved, the specific conditions for imports of the products concerned could be fixed. Until then, the Japanese authorities issued health certificates only in respect of fishery products exported to the Community from establishments which complied with the requirements of Directive 91/493.
The Community's mission of experts was sent out in order to ascertain what conditions prevailed in the fish-processing establishments in Japan, so that the specific conditions for imports of fishery products from that country could subsequently be fixed. Following that mission's negative findings, which were set out in the report of 4 April 1995, and the ensuing adoption of Commission Decision 95/119, the Japanese authorities suspended the issue of health certificates as from the beginning of May 1995, and on 7 August 1995 sent to the Commission a new list of two approved establishments. On 7 September 1995, they notified the Commission that they had approved another four establishments. Health certificates were again issued but only in respect of products from those establishments.

15. Following that visit, a 'preliminary report concerning a mission in Japan about the import of scallops and other fishery products', dated 4 April 1995, was produced.

16. The Community experts concluded that the establishments for scallops and fishery products which they had visited did not comply with the requirements of Directive 91/493 and that some establishments presented serious public health risks. Moreover, the checks by the competent authorities were not strict enough and gave no guarantee about the absence of fraud concerning the origin of the products.

17. The report by the Community experts reads as follows:

'1. General remarks

These remarks concern both establishments for scallops and for other fishery products.

1.1 The official authority (Ministry of Health and Welfare, assisted by the Health Centres of the Prefectures) does not carry out a satisfactory check on the establishments; some establishments presenting serious public health risks were put on the list of establishments by the Japanese authority and declared as complying with the requirements of Directive 91/493/EEC.

1.2 The Japanese legislation, for some points (health conditions for fishing vessels and for landing points, microbiological criteria for drinking water, temperature of frozen products ... is not equivalent to Community legislation.

1.3 The control of the critical points (Hazard Analysis Critical Control Points) is neither understood nor properly implemented by the establishments.

1.4 The guarantees for the use of drinking water in the establishments are clearly insufficient (deep well water not treated and not checked, municipal network water not checked frequently enough).

1.5 Batch identification (raw materials, products during processing and finished products) is not carried out most of the time and does not allow for the trace-back to origin (establishment and process).

2. Scallop establishments

...

3. Establishments for other fishery products

The mission visited four establishments, selected by the competent authority, and the Tokyo fish market.

3.1 The conditions of structure, equipment and hygiene in these four establishments, were not in compliance with the requirements of Council Directive 91/493/EEC.

3.2 In two establishments, in particular, in a cannery, the absence of hygiene and the bad manufacturing practices presented serious public health risks.

3.3 The deficiencies of the checks carried out by the competent authority (procedure to approve the establishments, regular inspections, approval of the private laboratories) and the improper identification of the production batches do not give any guarantee that the exported products meet the requirements of Council Directive 91/493/EEC and come from an approved establishment.

3.4 By letter of 22 March 1995, the Mission of Japan in Brussels provided the Commission with a list of 80 establishments which "meet the conditions laid down by Council Directive 91/493/EEC". None of the four establishments, selected by the Japanese authority, met these conditions, at the time of the visit.

4. Conclusion

The establishments visited for scallops and fishery products did not comply with Council Directive 91/493/EEC. Some presented serious public health risks.

The checks by the competent authority are not strict enough and give no guarantee about the absence of fraud concerning the origin of the products.' [13]

18. The experts also produced individual reports on visits to seven establishments, three of which are geared to processing scallops and four to other fishery products.

19. On the basis of that report by its experts, on 7 April 1995, pursuant to Article 19 of Directive 90/675/EEC, the Commission adopted Decision 95/119/EC concerning certain protective measures with regard to fishery products originating in Japan, [14] which provided as follows:

Article 1

'Member States shall prohibit the import of consignments of fishery products in whatever form originating in Japan.' [15]

Article 3

'Member States shall amend the measures that they apply to imports to comply with this decision. They shall inform the Commission thereof.' [16]

13 — Section 2 of the report, which relates to scallop-processing establishments, reads as follows:
'Thirteen establishments are on the list provided by the Japanese authority. During the visit, five establishments were supposed to be in operation, the seven others being located in areas where scallop harvesting was not open, due to weather conditions.
Out of these five establishments, the mission selected three establishments to be visited, and gave their names on the day of arrival in Tokyo (27 March). Some hours later, the mission was informed that one out of the three establishments was closed. Therefore, the mission insisted on carrying out a short visit, which made possible the discovery that this establishment was not meeting Community requirements.
2.1 The biotoxines (DSP and PSP) analytical methods, used by official and private accredited laboratories, are not fully harmonized.
2.2 The official analytical procedures showed that the matrix to be tested is not the ovary (as indicated in the Commission Decision of 8 April 1994), but the muscle, which does not concentrate the biotoxines.
2.3 In two out of three establishments visited, the mission found cartons of frozen scallop plastic bags (muscle and ovary) in cold stores, labelled in French "Frozen on 10 April 1990, best before 10 April 1992".
2.4 The identification system for process products cannot prevent fraud concerning products coming from non-approved establishments.
2.5 The three establishments visited did not meet the requirements concerning structure, equipment and hygiene, as laid down by Council Directive 91/493/EEC. Therefore, the Mission of Japan in Brussels, by letter of 22 December 1994, declared that the 13 establishments had met the requirements from that date on. They had received a provisional approval between 8 April 1994 and 31 December 1994, in order to have the opportunity to achieve the improvements necessary to respect the Community requirements.'

14 — Decision cited in footnote 1.

15 — That prohibition was subsequently only partly lifted. The article in question was replaced, in Commission Decision 95/537/EC of 6 December 1995 (OJ 1995 L 304, p. 51), by the following text:
'Member States shall prohibit the import of bivalve molluscs, echinoderms, tunicates and marine gastropods in whatever form originating in Japan.'

16 — Article 2 of Decision 95/119 reads as follows:
'Decision 94/206/EC is repealed'.
Decision 94/206 of 8 April 1994 (OJ 1994 L 99, p. 44) amended for the second time Commission Decision 92/91/EEC of 6 February 1992 on certain protective measures with respect to scallops originating in Japan (OJ 1992 L 32, p. 37), allowing the resumption of imports into the Community. Decision 92/91 prohibited the importation of scallops from Japan. This last decision was amended by Commission Decision 92/293/EEC (OJ 1992 L 155, p. 39) which extended the prohibition to all bivalve molluscs and marine gastropods originating in Japan.

Article 4

'This decision is addressed to the Member States.'

B — *The relevant national legislation*

20. In order to implement Commission Decision 95/119, the Netherlands Secretary of State for Public Health, Welfare and Sport, acting on the advice of the Minister of Agriculture, the Environment and Fisheries, adopted the Decree of 13 April 1995 [17] amending the Warenwetregeling Invoerverbod Bepaalde Visserijprodukten uit Japan (Decree, issued pursuant to the Law on Foodstuffs, prohibiting the importation of certain fishery products from Japan, hereinafter 'the Warenwetregeling'). [18]

21. The prohibition entered into force in the Netherlands on 15 April 1995.

22. Article 1 of the decree, as amended, provides that consignments of fishery products originating in Japan may not be introduced into Netherlands territory in any form whatever.

C — *The Agreement on the application of sanitary and phytosanitary measures*

23. The Community approved the Agreement on the application of sanitary and phytosanitary measures [19] by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994). [20]

24. Paragraphs 2 and 3 of Article 2 of the Agreement, headed 'Basic Rights and Obligations', read as follows:

'2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence ...

3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not

17 — *Staatscourant* 1995, p. 74.
18 — *Staatscourant* 1994, p. 86.

19 — This agreement has already been cited in footnote 3.
20 — OJ 1994 L 336, p. 1.

be applied in a manner which would constitute a disguised restriction on international trade.' [21]

25. Article 3, headed 'Harmonization' provides as follows:

'1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

2. ...

3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5(1).

...'

Footnote (1) to paragraph 3 reads as follows:

'For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.'

26. Article 5, headed 'Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection', reads as follows:

'1. Members shall ensure that their sanitary or phytosanitary measures are based on an

21 — Article 4 of the Agreement, headed 'Equivalence', reads as follows:
'1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.
2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.'

assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest-or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

5. ...

6. ... when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility (1).

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.'

The footnote to Article 5(6) reads as follows:

'For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.'

III — Facts

27. Affish BV (hereinafter 'Affish') imports, mainly from Japan, and distributes deep-frozen fishery products. Since 1980, it has maintained for that purpose relations with the trading house Hanwa Co. Ltd of Osaka (hereinafter 'Hanwa').

28. Hanwa represents four Japanese factories which further process 'Surimi', semi-processed fish, into Surimi fish products, known as 'kamaboko', [22] which are placed on the market in the Community as snacks.

29. Affish sells its products mainly to wholesalers in the Netherlands, Belgium, Germany, France and Spain.

30. Between 23 January 1995 and 15 March 1995, Affish purchased 11 consignments of Surimi products from Hanwa.

31. At the end of March 1995, Hanwa shipped to the Netherlands two of those consignments of kamaboko, in respect of which health certificates had been issued by the competent Japanese authorities.

32. By decision of 2 May 1995, issued on the basis of Commission Decision 95/119, the Rijksdienst voor de Keuring van Vee en Vlees (National Department for the Inspection of Livestock and Meats, hereinafter 'the

22 — According to the order for reference, the fish caught is semi-processed at sea into 'Surimi' products which are further processed in the Japanese factories; the resultant product is called 'kamaboko'.

Rijksdienst') refused to allow the importation of the said consignments into the Netherlands.

33. On 3 May 1995, Affish lodged an objection against the Rijksdienst's decision.

34. By application of 3 May 1995, Affish asked the President of the College van Beroep voor het Bedrijfsleven, by way of interim relief, to suspend the enforcement of the Rijksdienst's decision and to declare that the Rijksdienst is entitled to refuse to allow the importation of the aforementioned consignments of fishery products, and of any consignments of fishery products which Affish may import in the future, only on grounds of the protection of health and life of humans or animals, and that the Rijksdienst would be entitled to base such refusal only on a laboratory investigation, conducted or commissioned by the Rijksdienst, showing that an actual threat to the health and life of humans or animals would result from the importation of the consignments in question.

35. In support of its application to the national court, Affish claimed that contested Decision 95/119 was invalid on the following four grounds: (a) it conflicted with Article 19 of Directive 90/675, (b) it infringed the principle of proportionality, (c) it infringed the principle of equal treatment and (d) it was in breach of Articles 2, 4 and 5 of the Agreement. In the alternative, Affish claimed that the Netherlands had infringed the principle of the protection of legitimate expectations, enshrined in Community law, by failing to provide for a transitional arrangement for consignments which had already been shipped.

36. Against that, the Rijksdienst argued that the Netherlands authorities were obliged to comply fully with the Community decision and were not competent to consider the question whether the decision had been lawfully adopted: that was a matter for the Court alone. Since the decision did not provide for a transitional period, the Netherlands Government could not provide for one either.

37. The national court first considered Affish's claim in the alternative and dismissed it on the ground that neither contested Decision 95/119 nor Directive 90/675, nor Community law in general, contains provisions which would allow the Member States, in implementing the decision, to provide for a transitional arrangement. Furthermore, assuming that the protection of public health within the meaning of Article 19 of Directive 90/675 was actually at stake, there would be no room for taking into account the economic interests of affected traders.

38. The national court went on to consider the extent to which the requirements set out by the Court in its judgment in the *Zuckerfabrik* case [23] had been met in order for the national court to suspend the operation of a national administrative act based on an act of a Community institution (Community regulation). In its view, there were strong reasons to doubt the validity of the contested decision.

39. The national court questions the procedure followed by the Commission in adopting the decision. It considers that the aim of the mission of experts was to inspect the state of the fish-processing establishments in Japan in order subsequently to fix, in accordance with Article 11 of Directive 91/493, the specific conditions for the importation of fish products. In the national court's initial assessment, however, the findings of the mission of experts do not provide conclusive justification for the decision.

40. The national court goes on to consider that, of the many dozens of establishments which exist in Japan, the experts visited only four in the north-east of the country. The conclusions in the report do not justify a general prohibition on the importation of fishery products from Japan, because it is not clear that the conditions found at the four establishments were representative [24] of all the establishments, or that supervision by the authorities was also inadequate in the other regions of Japan, in view of the fact that Affish obtains its products from establishments in regions other than those visited by the experts. No general prohibition on the importation of fishery products should therefore have been imposed.

41. The national court further points out that the prohibition affects a particular market, namely, the market in kamaboko products, which, at least in the Netherlands, had hitherto been free of problems. In addition, any unreliability of the health certificates issued for certain types of product can be offset by checks at the time of importation of the products concerned into the Community. Moreover, it observes that the results of the inspections do not seem to have been discussed with the persons concerned before the contested decision was adopted.

42. The national court further considers that the fact that the Commission was not represented at the hearing, although it had been

23 — Joined Cases C-143/88 and C-92/89 *Zuckerfabrik Süderdithmarchen and Zuckerfabrik Soest* [1991] ECR I-415, paragraph 16 et seq. The conditions set out by the Court in that judgment were clarified in Case C-466/93 *Atlanta Fruchthandelsgesellschaft (II)* [1995] ECR I-3799, paragraph 35 et seq.

24 — At one of the establishments, the conditions were even assessed as 'satisfactory'.

invited to attend by the Rijksdienst, in order to explain the conclusions of the mission of experts on which it had based its decision, hindered a proper appreciation of the report. [25]

43. Finally, the national court considers that the market on which Affish offers the product in question for sale will very soon be lost through competition from other, similar products from other countries, and that, in view of the proportion of Affish's total sales accounted for by the product, it will inevitably become insolvent as a result of the import prohibition. In those circumstances, according to the national court, the requirement for urgency, as set out by the Court in the *Zuckerfabrik* case [26] for granting the interim relief sought, is satisfied, without any financial interests of the Community being involved which would preclude the grant of relief.

44. Although the national court maintained its reservations as regards the supervision and health checks carried out by the competent Japanese authorities at the establishments in the region from where Affish imports its products, and thus as regards the reliability of the health certificates issued, and therefore held, having regard to the overriding interest of the protection of public health, that the threefold inspection of imported fishery products provided for in Directive 91/493 [27] was not conclusive, it granted Affish's application and ordered the suspension of the contested Commission decision, instructing the Rijksdienst: (a) to have the consignments of fishery products which Affish was prohibited from importing into the Community investigated as thoroughly as possible in accordance with the present state of the art for possible defects from the point of view of the protection of health and life of humans and animals and (b) to release the said consignments for circulation in the Community only if they were shown to a sufficient extent by the aforesaid investigation to have no such defects. At the same time, it requested the Court to give a preliminary ruling on the validity of Commission Decision 95/119.

IV — The question submitted by the national court

45. The College van Beroep voor de Bedrijfsleven has referred the following question to the Court for a preliminary ruling:

'Regard being had to the considerations set out in this order, is Commission Decision

25 — The Commission was in fact represented at the hearing in a later case before the same court and between the same parties (concerning a prohibition on the importation of further consignments of kamaboko, pursuant to Decision 95/119), in which judgment was given on 24 August 1995.

26 — Already cited in footnote 23.

27 — That is, a documentary check, an identity check and, finally, a physical check.

95/119/EC of 7 April 1995 valid in so far as it extends to Surimi fish products, also referred to as kamaboko, as imported by the applicant, which come from regions of Japan other than those in which the establishments investigated by a mission of experts from the Commission were located according to their report of 4 April 1995, or at least from establishments other than those investigated, and in relation to products which, following appropriate investigation upon their importation into the Community, showed no sign of health risks?'

V — Answer to the question submitted

Preliminary observations

46. It should be observed first of all that Affish applied to the national court for the suspension of the Rijksdienst's decision. According to the operative part of the order for reference, the national court has suspended the enforcement of Commission Decision 95/119. I am, however, of the opinion that the national court, doubting the validity of contested Decision 95/119, has in substance suspended the enforcement of the administrative act of the competent national authority [28] prohibiting the importation of certain consignments of fishery products from Japan, a decision which was adopted pursuant to the Warenwetregeling, which was in turn amended in order to give effect to the Commission's decision in the Netherlands. I am thus of the opinion that the national court has made an error, because it could not have suspended an act of a Community institution, namely the contested Commission decision, since the validity of such acts can be reviewed and, if necessary, suspended only by the Court; the national court suspended only the national act implementing the decision. However, that error cannot be subject to review by the Court.

47. Having clarified that, I shall first examine whether it is necessary to supplement the judgment in *Zuckerfabrik* [29] with a further requirement, this time of a procedural nature, for the grant of interim relief when a national court questions the validity of a Community act (A). Next, the grounds raised against the validity of Commission Decision 95/119, both by the national court and by Affish in its observations to the Court, must be examined. [30] I shall thus

28 — The Italian and the Netherlands Governments point this out in their observations.

29 — Already cited in footnote 23.

30 — The national court points out that the other grounds relied upon by Affish in order to contest the validity of the decision concern the proportionality of the measure at issue, viewed in the light of the requirements set forth in Article 19 of Directive 90/675. I am of the opinion that all of Affish's arguments must be examined in turn, even though the national court has not taken a view on any particular argument. The Court's case-law is clear on this point. In the judgment in Joined Cases 103/77 and 145/77 *Scholten-Honig* [1978] ECR 2037, paragraphs 16 and 17, the Court considered the validity of a Community regulation on the basis of the grounds for annulment relied on by the plaintiff in the main proceedings, since the national court had asked the Court in general terms for a ruling on the question whether the regulation in question was valid.

consider to what extent the Commission, in adopting the decision, acted in breach of Article 19 of Directive 90/675 by not giving a sufficient statement of reasons for its decision, in so far as there was no reference to 'serious reasons' which would justify such a restrictive measure (B). I shall go on to examine whether the Commission infringed the principle of proportionality (C), the principle of equal treatment (D), the principle of the protection of legitimate expectations (E), the provisions of the Agreement on the application of sanitary and phytosanitary measures (F) and, finally, whether it was guilty of misuse of powers or abuse of process (G).

(A) *The need to supplement the judgment in Zuckerfabrik*

(1) Admissibility

48. In its order for reference, the national court merely observes that the fact that the Commission was not represented at the hearing, despite being invited to attend by the President at the request of the Rijksdienst, hindered the proper assessment of the conclusions set forth in the experts' report on their visit to the establishments concerned, and consequently also the examination of the validity of the contested decision.

49. According to the Commission, this case gives the Court an opportunity to rule for the first time on the question whether the requirements set out in the *Zuckerfabrik* judgment for suspension by the national court of a national administrative act based on an act of a Community institution, the validity of which is contested, must be supplemented by the requirement that the national court give the Community institution an opportunity to make its point of view known before suspending the act.

50. I am of the opinion that it is not necessary for the Court to take a view on this point. My objection is that the national court has not directly raised this question. [31] It is true that there have been a number of occasions when the Court has interpreted provisions even though the national court did not expressly request it to do so. [32] However, on each occasion when it did so, this was solely in order to give the national court a helpful reply which would enable it subsequently to resolve the dispute pending before it. I am thus of the opinion that an answer to this question is neither necessary nor useful for the purpose of answering the question referred by the national court for a preliminary ruling, nor does it have to be answered

31 — The national court did invite the Commission to explain its point of view at the hearing, even though the Commission was unable to attend.
As was observed at the hearing, instances can be cited (as in the United Kingdom, for example) in which the national court has called on the Community institution to explain the reasons why it adopted a particular act.

32 — See, for example, Case 70/77 *Simmenthal* [1978] ECR 1453, paragraph 57; Case C-114/91 *Claeys* [1992] ECR I-6559, paragraph 21 in conjunction with paragraph 10; Case C-280/91 *Viessmann* [1993] ECR I-971, paragraph 17, and the Opinion of Advocate General Jacobs in that case (point 14).

in order to enable the national court to resolve the dispute before it. [33]

(2) Substance

51. With regard to the question of the extent to which it is necessary to supplement the *Zuckerfabrik* judgment and, more specifically, whether it is necessary for the Court to lay down procedural rules governing the manner in which national courts grant interim relief, [34] I must observe that the Court is being asked by the Commission to lay down a procedural rule which would guarantee the right of the Community institutions to defend themselves in the event of the validity of one of their acts being called into question. In that way, the Community institution would be able, if it so wished, to put forward its point of view and provide the national court with an explanation of the reasons which prompted it to adopt the contested measure. In other words, it would then no longer be necessary for the national court to summon the Community institution in order to make its point of view known: the Community institution would be entitled to do so as of right. [35]

52. Although the recognition of such a requirement is theoretically of interest, I am not in favour of it. The national court cannot assess the validity of a Community act, and it must therefore refer a question for a preliminary ruling whenever it has doubts about the validity of such an act. The proper forum for dealing with such a question is the Court. Apart from that, the Community institution will not wish to run the risk of having its decision annulled by the national court. I believe that the national court would derive little benefit from the explanation given by the Community institution, which can in any case put its point of view to the Court later on if a reference for a preliminary ruling is made on the matter. Under the case-law established by the *Zuckerfabrik* judgment, [36] the national court can suspend only the enforcement of a national administrative act based on an act of a Community institution, and at the same time refer a question to the

33 — In my opinion, this is the only view which accords with the purpose of Article 177 of the Treaty and finds support in the settled case-law of the Court which has repeatedly held that the duty assigned to it under Article 177 is that of assisting in the administration of justice in the Member States (see Case 244/80 *Foglia* [1981] ECR 3045, paragraph 21; Case C-231/89 *Gmurzynska-Bscher* [1990] ECR I-4003, paragraph 20; Case C-346/93 *Kleinwort Benson* [1995] ECR I-615, paragraph 24; and Case C-415/93 *Bosman* [1995] ECR I-4921, paragraph 60), and not that of delivering advisory opinions on general or hypothetical questions unconnected with the resolution of the pending dispute; see *Foglia*, already cited, paragraphs 18 and 20, and Case 149/82 *Robards* [1983] ECR 171, paragraph 19. See also Joined Cases C-422/93, C-423/93 and C-424/93 *Zabala* [1995] ECR I-1567, paragraph 29.

34 — Let me point out that the national court invited the Commission to explain its point of view at the hearing, but that the Commission was prevented from doing do for reasons unconnected with the case. It was, however, represented during the hearing of a later application for similar judicial relief, brought by Affish before the same court.

35 — In practice, this would mean that the Parliament would have the right to defend itself whenever any of its acts produced legal effects or was adopted in accordance with the co-decision procedure under Article 189b of the Treaty, that is, jointly with the Council, the Commission and the European Central Bank.

36 — Already cited in footnote 23.

Court for a preliminary ruling on the validity of the Community act, thereby avoiding lengthy protraction of the proceedings. [37]

(B) *Insufficient statement of reasons for the Commission's decision*

53. According to Affish, in adopting Decision 95/119, the Commission infringed Article 19 of Directive 90/675 in several respects. In particular, it argues that the Commission cannot be regarded as the Community legislature, and that it therefore does not have a wide discretion under Article 19. But even if it did have such a discretion, it would still have to give a proper statement of the legal and factual reasons forming the basis of a measure as restrictive as an import prohibition in respect of fishery products from Japan, namely the Surimi products imported by Affish, which had hitherto undergone all veterinary checks inside and outside the Community without any problem. [38]

(1) Extent of the Commission's powers under Article 19 of Directive 90/675

54. In the first place, Article 43 of the Treaty is cited as the legal basis for Directive 90/675 which in turn formed the basis of the contested decision; in terms of its substance, moreover, the contested decision falls within the scope of the common agricultural policy, an area in which the Community institutions generally have a wide discretion in view of the tasks which the Treaty assigns to them. [39]

55. Article 19 of Directive 90/675 confers exclusively on the Commission a wide discretion since, 'depending on the gravity

37 — In addition, the national court can always ask the Community institution which adopted the measure for information in order to obtain a clear picture of the factual context of the dispute pending before it; see, for example, the order of 13 July 1990 in Case C-2/88 Imm. *Zwartfeld* [1990] ECR I-3365.

38 — At the hearing, Affish argued that the hypothetical risk from hygiene deficiencies at the fish-processing establishments was very small because the fish used for Surimi is caught in Alaska and Canada and processed into semi-finished products at sea.

39 — The Court has ruled on the Commission's powers in this field in Case 27/85 *Vandemoortele* [1987] ECR 1129, paragraph 14. In that judgment, which concerned the scope of the implementing powers granted in principle to the Commission in regard to the common agricultural policy, the Court held (paragraph 14) that 'it follows from the context of the Treaty in which Article 155 must be placed and also from practical requirements that the concept of implementation must be given a wide interpretation'. Since 'only the Commission is in a position to keep track of agricultural market trends and to act quickly when necessary, the Council may confer on it wide powers of discretion and action in that sphere, and when it does so the limits of those powers must be determined in the light of the essential general aims of the market organization'.
With regard to the Council's powers in the context of the common agricultural policy, see, for guidance, Case C-122/94 *Commission* v *Council* [1996] ECR I-881, paragraph 18, which deals with State aid in the wine sector, and my Opinion in that case, as well as the earlier judgment in Case 138/79 *Roquette Frères* [1980] ECR 3333, paragraph 25.

of the situation', it has to act without delay if, in the territory of a third country, a zoonosis or other disease occurs or spreads which is 'liable to present a serious threat' to animal or human health, or if such action is warranted by any other 'serious' animal or public health reason, in particular 'in the light of the findings of its veterinary experts'.

56. Article 19 of the directive thus employs a series of broadly-based legal concepts, such as 'serious threat to animal or public health', 'serious animal health or public health reason', 'gravity of the situation', to be defined by the Commission, subject to review by the Court.

57. To my mind, the question of what facts or situations ultimately constitute a 'serious threat', 'serious reasons' or a 'grave situation' must be assessed from case to case, taking account of many factors such as, for example, the nature of the product, its possible susceptibility to rapid deterioration, or the possibility of thorough and conclusive checks at both the production stage and during transport or on release for consumption. [40]

58. In exercising the power conferred on it by Article 19 of the directive, the Commission acts as the Community legislature since in a given situation it can take action to regulate a problem by adopting one of the measures specified in that provision.

59. That wide discretion is given to the Commission in the framework of a system of safeguards within the overall organization of veterinary checks on products entering the Community from third countries, to be used in serious and exceptional circumstances. [41]

40 — However, the Commission's wide discretion does not mean that there is no supervision of the decisions which it adopts in exercising its powers. If the indeterminate legal concepts contained in Article 19(1), whose more precise definition is left to the Commission's discretion, were excessively widened, they would cease to be effective. Those concepts cannot cover every symptom of disease or zoonosis, or any kind of circumstance, because their meaning would then be lost and, as indeterminate legal concepts, they would have merely nominal status without any substantive binding effect or, ultimately, any practical utility.

41 — The sixth recital in the preamble to Directive 90/675 states that 'provision must be made for safeguard arrangements; ... in this context, the Commission must be able to act, particularly by visiting the places concerned and adopting measures appropriate to the circumstances'.

60. In my opinion, it is clear from Article 19 (1) of Directive 90/675 that discretion is conferred on the Commission in order to enable it to take preventive action for the protection of public health by suspending imports from third countries. More specifically, it has the power to act on its own initiative or at the request of a Member State, without delay and depending on the gravity of the situation, to order the suspension of imports from part or all of the territory of the third country concerned, or else to lay down specific conditions in respect of products coming from part or all of the territory of the third country concerned, in particular in the light of the findings of its veterinary experts. The Commission can act not only when, in the territory of a third country, a disease or zoonosis occurs or spreads, from which a serious threat to human and animal health is likely to arise, but also if such action is warranted by other serious animal health or public health reasons.

61. To my mind, it is clear from Article 19 of Directive 90/675 that the Commission can prohibit imports of, in this case, fishery products for as long as it deems it necessary, not only in the event of an actual threat from imports of fishery products which appear harmful to public health (because they have deteriorated, for example), but also when veterinary checks in the country of export are either completely absent or seriously defective, that is, where the veterinary checks carried out in that country are seriously inadequate, regardless of whether or not an actual threat to public health has arisen. In other words, the Commission can prohibit imports in order to prevent consumption, not only of products which threaten public health, but also of products insufficiently checked, once it has serious reasons for believing that either circumstance applies.

62. The Court has ruled in many cases not only on the extent of the powers of the Community institutions pursuant to Treaty provisions relating to the implementation of the common agricultural policy, but also on the limits of its powers of review when those institutions enjoy a wide discretion and have to evaluate a complex economic situation. Thus the Court has taken the view that, in the case of a common organization of the market in certain products, [42] 'in reviewing the exercise of such a power the Court must confine itself to examining whether it contains a manifest error or constitutes a misuse of power or whether the authority in question did not clearly exceed the bounds of its discretion'. [43]

42 — According to the first recital in the preamble to Directive 91/493, the directive was adopted with a view, among other things, to ensuring 'the smooth operation of the common organization of the market in fishery products'.

43 — In other words, when the institution adopting the decision has wide discretion, the Court, which has no power to substitute its own assessment for that of the institution — in this case the Commission — adopting the decision, must establish with a reasonable degree of certainty, on the basis of the evidence produced by the parties, that the institution has not exceeded the bounds of its discretion; that there was no manifest error concerning the facts which could affect the validity of the decision, that there was no misapplication of excessively vague legal concepts, that the decision was not adopted by misuse of powers, that there was no manifest error in the assessment of the facts, and that the reasons stated for the decision are valid in law; see *Roquette Frères*, cited in footnote 39, paragraph 25; Case 166/78 *Italy* v *Council* [1979] ECR 2575, paragraph 14; and the judgment cited in footnote 39 in Case C-122/94 *Commission* v *Council* [1996], paragraph 18. See also the concluding sentence of point A of the Opinion of Advocate General Gand in Case 8/65 *Acciaierie e Ferriere Pugliesi* [1966] ECR 1.

63. I shall examine in turn each of the grounds raised by Affish, in particular to what extent the circumstances which led the Commission to adopt Decision 95/119 constitute sufficient justification for legal purposes, in other words whether or not the statement of reasons is defective.

(2) Sufficient statement reasons for the contested decision

64. It should first be recalled that, under Article 190 of the Treaty, acts of the Community institutions must state the reasons on which they are based. As the Court has consistently held, however, [44] the statement of reasons required by Article 190 must be 'appropriate to the nature of the measure in question. It must show clearly and unequivocally the reasoning of the institution which enacted the measure so as to inform the persons concerned of the justification for the measure adopted and to enable the Court to exercise its powers of review. It has also been held that the statement of reasons for a measure is not required to specify the matters of fact or of law dealt with, provided that it falls within the general scheme of the body of measures of which it forms part'.

65. In this connection, I should point out that a statement of reasons for an act is insufficient if it does not mention the factual circumstances on the basis of which the institution concerned reached its assessment, even though there are reasons which justify the adoption of the decision, and do not give a sufficiently clear statement of the objectives pursued. [45]

66. The first recital in the preamble to contested Commission Decision 95/119 reads as follows: 'Whereas a mission of experts of the Commission went to Japan to check the conditions of production and processing of fishery products exported to the Community; whereas according to the observations of these experts, the official guaranties given by the Japanese authorities are not adhered to and the conditions of production and storage of fishery products show serious defects as regards hygiene and control which can constitute risks to public health'.

67. The second recital in the preamble reads as follows: 'Whereas Commission Decision 94/206/EC prohibits the import of consignments of bivalve molluscs and marine gastropods originating in Japan other than scallops and other *Pectinidae*, frozen or processed'.

44 — See, for example, Case C-353/92 *Greece* v *Council* [1994] ECR I-3411, paragraph 19; Joined Cases C-63/90 and C-67/90 *Portugal and Spain* v *Council* [1992] ECR I-5073, paragraph 16; *Atlanta Fruchthandelsgesellschaft II*, cited in footnote 23, paragraph 16; and *Commission* v *Council*, cited in footnote 39, paragraph 29.

45 — See Case C-331/88 *Fedesa* [1990] ECR I-4023, paragraph 29, and Case 68/86 *United Kingdom* v *Council* [1988] ECR 855, paragraph 28.

68. On the basis of the conclusions of the mission of experts, the Commission found, as stated in the third recital in the preamble, that 'it is necessary to suspend the import of all fishery products originating in Japan pending improvement of the conditions of hygiene and control of production'.

69. Examination of the Community experts' report shows that they directed their observations (sections 2 and 3 of the report) primarily at the serious shortcomings of the veterinary checks carried out by the competent Japanese authorities, at the same time pointing out the serious public health risks which existed at the time of the visits (see, in particular, points 1.4, 2.3 and 3.2 of the report).

70. The report as a whole, to which the first recital expressly refers, but especially point 3 therein, sets out the reasons why the conditions at the fish-processing establishments visited, in particular their structure, equipment and hygiene, the manufacturing practices and the deficiencies in the veterinary checks carried out by the competent Japanese authorities, were not only inconsistent with the provisions of Directive 91/493, but also presented serious public health risks. In view of the nature of the fishery products concerned, which, as the Commission points out, can only be effectively checked at the production stage, there were thus serious reasons for adopting measures for the protection of public health. I therefore consider that the statement of reasons for the contested Commission decision, which refers in general terms to the negative conclusions in the report, is neither insufficient nor incorrect since it can be assumed that the conditions laid down in Article 19 of the directive, on which the decision is based, had been fulfilled.

71. I am likewise of the opinion that the statement of reasons for the contested Commission decision may not be regarded as insufficient because it is too brief. It is true that the reasons in question do not include an exhaustive enumeration of all the factors in the Commission's reasoning, do not cite in full the conclusions of the mission of experts sent out to Japan, and do not explain why a less restrictive measure would not have been appropriate. However, as an act adopted under a discretionary power, the contested decision does contain, albeit in summarized form, mention of factual circumstances which the Commission took into consideration, and the legal conclusions justifying its adoption. It is precisely because the decision is an act based on a discretionary power that a summary statement of reasons is sufficient, as Advocate General Lagrange has also pointed out. [46]

46 — See his Opinion in Joined Cases 36/59, 37/59, 38/59 and 40/59 *Geitling* v *High Authority* [1960] ECR 423.

72. The serious defects as regards hygiene and control by the Japanese authorities are, in my view, characteristic circumstances which may constitute 'a serious animal health reason' or present a threat to 'public health'.

73. As a whole, therefore, the preamble to the decision forms a statement of reasons which must be considered sufficient for the purposes of Article 190 of the Treaty with regard not only to its wording but also to the factual circumstances which led to its adoption (reference to 'serious defects as regards hygiene and control') and all the rules of law governing the matter in question. [47]

(C) *Infringement of the principle of proportionality*

74. Affish considers that the contested decision infringes the principle of proportionality which also governs Article 19 of Directive 90/675. [48] In particular, it maintains that the measure selected by the Commission was neither appropriate nor necessary for achieving the objective pursued and that the possibility of adopting a less drastic measure was not examined. Finally, according to Affish, the disadvantages of the measure selected outweigh the advantages.

(1) Was the measure adopted appropriate to the objective pursued?

75. According to Affish, the fact that the local authorities in a particular region of Japan failed to carry out the necessary veterinary checks cannot justify the adoption of such a restrictive measure by the Commission.

76. As the national court observes, points 1.3 to 1.5 of the report indicate that insufficient attention was paid to critical aspects of the production process, such as water supply, for example, and verification of every batch. It also notes that the four establishments from which Affish obtains its products comply fully with the Community requirements. It points out that the conclusions of the mission of experts [49] are not a sufficient basis for such a restrictive measure since there had been no actual complaints about particular products which could justify the adoption of safeguard measures under Article 19 of

47 — See also, for example, Case 185/83 *University of Groningen* [1984] ECR 3623, paragraph 38; Case 203/85 *Nicolet Instrument* [1986] ECR 2049, paragraph 10; Case 167/88 *Association générale des producteurs de blé et autres céréales* [1989] ECR 1653, paragraph 34; Joined Cases C-121/91 and C-122/91 *CT Control and JCT Benelux* [1993] ECR I-3873, paragraph 31.

48 — According to Affish, Article 19 contains a double proportionality test, because on the one hand the reasons justifying the measures adopted must be stated, and on the other, the measure selected must be commensurate with the situation which has arisen.

49 — Neither the national court nor Affish disputes the reliability of the conclusions of the mission of experts with regard to the establishments visited.

Directive 90/675, as had been the case earlier with scallops and had ultimately led to their prohibition.

77. Those arguments cannot be accepted.

78. According to settled case-law, by virtue of the principle of proportionality, 'measures imposing financial charges on economic operators are lawful provided that they are appropriate and necessary for meeting the objectives legitimately pursued by the legislation in question. Of course, when there is a choice between several appropriate measures, the least onerous measure must be used and the charges imposed must not be disproportionate to the aims pursued.' [50]

79. With regard to the question of the extent to which those conditions are amenable to judicial review, the Court has consistently held [51] that 'in matters concerning the common agricultural policy, the Community legislature has a discretionary power which corresponds to the political responsibilities imposed by Articles 40 and 43 of the Treaty. Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution intends to pursue.'

80. I must therefore begin by examining the objective of the contested decision (95/119) in order to determine thereafter whether the measure adopted by the Commission is appropriate and necessary in order to achieve that objective, and whether its disadvantages outweigh its advantages.

81. It is clear from the first recital in the preamble that the objective of the decision is the protection of public health which would be put at risk by the consumption of fishery products from Japan since serious defects as regards hygiene have been found to exist.

82. In its recent order in the case concerning bovine spongiform encephalopathy (BSE — or 'mad cow disease'), [52] the Court, in balancing the conflicting interests, pointed out that Article 3(o) of the EC Treaty provides that the objectives of the Community

50 — See, for example, Case 265/87 *Schräder* [1989] ECR 2237, paragraph 21; *Fedesa*, cited in footnote 45, paragraph 12; Case C-295/94 *Hüpeden* [1996] ECR I-3375, paragraph 14; and Case C-296/94 *Pietsch* [1996] ECR I-3409, paragraph 15.

51 — See, for example, *Schräder*, cited in footnote 50, paragraph 22; Case C-331/88 *Fedesa*, cited in footnote 45, paragraph 14; and Case C-280/93 *Germany* v *Council* [1994] ECR I-4973, paragraphs 89 and 90.

52 — Order of 12 July 1996 in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903.

include 'a contribution to a high level of health protection'. The Court went on to state: 'That objective is reiterated in the first subparagraph of Article 129(1) of the Treaty, under which the Community is to contribute towards ensuring a high level of human health protection. The third subparagraph of Article 129(1) further specifies that health protection requirements are to form a constituent part of the Community's other policies.' [53] It is significant, moreover, that in that order the Court considered that 'efforts to achieve the objectives of the common agricultural policy cannot disregard requirements of public interest, such as the protection of consumers or of the health and life of humans and animals, which the Community institutions must take into account in exercising their powers.' [54]

83. In the light of that case-law, I am of the opinion that the measure adopted by the Commission, namely the prohibition of imports of all fishery products from Japan, was appropriate for the achievement of the objective pursued, which is undoubtedly of a higher order, namely the protection of public health. That is because of the inadequate standard of the veterinary checks carried out by the competent Japanese authorities on the establishments visited by the Community experts (section 1 and points 3.1 and 3.2 of the report) and the public health risks presented by the defects identified. [55]

(2) Was the measure adopted necessary?

84. According to Affish, the problem of defective control arises only in a different region of Japan from that where Affish obtains its products, and a general prohibition on imports from Japan was not a measure which was necessary to achieve the objective pursued.

85. The national court points out that the conclusions of the Community experts cannot be representative since at one of the establishments inspected the conditions were regarded as 'satisfactory'. Moreover, inspections were carried out at only a very small number (four) of establishments in a specific region of Japan, which was not that where Affish obtains its products.

53 — Paragraph 63.

54 — Paragraph 63; see also Case 68/86 *United Kingdom* v *Council*, cited in footnote 45, paragraph 12.

55 — As the Commission explained during the hearing, the deficiencies in veterinary control are attributable to the legal system in force in Japan. While the central authorities lay down general rules with which all the regional authorities have to comply, there is nevertheless no central monitoring of compliance with those rules by the decentralized local authorities.

(a) Inspections by sampling

86. In considering the need for the measure adopted by the Commission, the question arises of how far the results of an inspection by sampling can suffice to justify the general prohibition on fishery products from Japan imposed by the Commission. This is all the more relevant since both Affish and the national court observe that veterinary inspection of production in Japan is decentralized and there is no central supervisory authority: it does not mean, however, that inspection is also so deficient in other regions of that country that all importation must be prohibited.

87. In my opinion, on-the-spot inspections by sampling were the proper way to verify conditions at Japanese fish-processing establishments which, as is clear from the experts' reports and as pointed out by the Commission at the hearing, did not comply with Community requirements. The Commission was therefore entitled to draw conclusions about the general conditions prevailing in those establishments in accordance with the law of probability, that is, by the broad method of extrapolation.

88. Support for this view can be found in the case-law of the Court, which has held that the Commission may base its action on the results of an inspection by sampling carried out in a sufficiently reliable manner, and on the conclusions of experts, that is, scientists with specialized knowledge who are able to make a full assessment of the actual situation [56] and to produce a report on the basis of their findings in relation to the whole [57] of which they have inspected certain parts. [58]

89. The Court has also held that, in the absence of specific rules governing the

56 — See Case C-269/90 *Technische Universität München* [1991] ECR I-5469 concerning exemption from import duty for a scientific instrument on the ground that there were no equivalent instruments in the Community. Having stated that 'the Commission has admitted that it has always followed the opinions of the group of experts because it has no other source of information concerning the apparatus being considered', the Court went on to hold that 'in those circumstances, the group of experts cannot properly carry out its task unless it is composed of persons possessing the necessary technical knowledge in the various fields in which the scientific instruments concerned are used or the members of that group are advised by experts having that knowledge' (paragraphs 21 and 22).

57 — See Case C-413/92 *Germany* v *Commission* [1994] ECR I-3781, paragraph 13, which concerned the grant of aid for processing skimmed milk into casein and caseinates. In that judgment, the Court held that, in relation to the supervision to be exercised by the national intervention agency, the term 'regular supervision' in Article 3(3) of Regulation No 756/70 of the Commission of 24 April 1970 on granting aid for skimmed milk processed into casein and caseinates (OJ, English Special Edition (I), p. 201) implies that if it appears from the official analysis that some of the batches which satisfied the internal checks carried out by the manufacturing concern do not in fact comply with the requirements of that regulation and thus cannot be considered eligible for aid, the national authorities must carry out further checks in order to ascertain whether the other batches for which an application for aid has been submitted do in fact comply with the requirements of the regulation or make the appropriate extrapolation in accordance with the law of probability.

58 — In Case C-385/89 *Greece* v *Commission* [1992] ECR I-3225 concerning clearance of the EAGGF accounts, the Court reviewed the legality of the Commission decision in question, which was adopted on the basis of the results of an inspection by sampling, and held that 'although the Commission must adopt appropriate and reliable methods of inspection, it is for the applicant Member State ... to adduce evidence that the methods adopted by the Commission were not appropriate for the type of inspection to be carried out and that the results obtained were unreliable' (paragraph 25).

conduct of inspection by sampling, the Commission may apply the methods of inspection which it considers to be most appropriate, [59] subject, however, to the general requirement that the methods chosen are reliable. [60]

90. In this case, there is no lack of rules concerning the requirements with which fish-processing establishments must comply, as the annex to Directive 91/493 shows, but there are no rules on the number of establishments to be inspected. Since the Commission cannot in practice stipulate that all fish-processing establishments in Japan which export products to the Community must be inspected, I take the view that it was entitled to be satisfied with the results of the inspection by sampling, that is, to base its action on the findings of the Community experts after a representative number of establishments had been inspected, and from those to draw its conclusions concerning the general state of the fish-processing industry in Japan.

91. Since Affish has not shown that all the establishments from which it obtains its products comply with Community requirements, its argument that the Commission was not entitled to base its decision on the conclusions of the mission of experts which it had sent out to inspect the fish-processing industry in a third country cannot be accepted.

(b) Need for the measure adopted

92. According to the Commission, a general prohibition on imports of fishery products from Japan was necessary for the effective protection of public health.

93. As the Commission rightly argues, the prohibition on imports could not have been restricted only to one particular region where the problem was localized by the inspections, or only to particular establishments, for three reasons:

(a) The fact that the Japanese authorities themselves had designated the establishments to be inspected [61] and thus the region where inspection would take place, [62] and where the conditions of

59 — See point 34 et seq. of the Opinion of Advocate General Gulmann in Case C-385/89 *Greece* v *Commission*, cited in footnote 58.

60 — See Joined Cases C-161/90 and C-162/90 *Petruzzi and Longo* [1991] ECR I-4845, paragraphs 17 and 18, which concerned the examination by sampling of certain characteristics of olive oil.

61 — It stands to reason that the establishments which they selected are among the average, if not the best.

62 — As stated by the Commission at the hearing, in reply to a question from the Court on this point.

hygiene were subsequently found to be unsatisfactory, led the Commission to assume that conditions at establishments not visited by the Community experts would be comparable.

(b) As the experts point out in their report (point 3.3), because of the deficiencies in the checks carried out by the competent Japanese regional authorities and the incorrect identification of batches of fish, there is no guarantee that the exported products complied with the requirements of Directive 91/493 and came from an approved establishment. Moreover, as the Commission has pointed out both in its written observations and at the hearing, since there is no central supervisory authority for the whole of Japan, any restriction of the prohibition to particular regions would by no means guarantee that products from an establishment situated in an 'uncontaminated region' where all the veterinary requirements had been met were not mixed with products from other regions. [63]

(c) According to the Commission and the Netherlands Government, an import prohibition is more effective than inspection on importation because, due to the nature of fishery products, which are liable to deteriorate quickly and present a health risk, veterinary inspection at source, that is, at the production stage, [64] is more appropriate. Inspection of fishery products is more effective where it is carried out before packaging, when products are still in unsorted piles and relatively easy to inspect in greater quantities. Moreover, inspection at the production stage is the rationale underlying the Community's directives on veterinary health inspections, and in particular Directive 91/493. [65]

94. Inspection of every batch of packaged fishery products must naturally take place by way of sampling since inspection of all the packages would not be feasible financially and would take so long that the product could deteriorate. Nevertheless, it could not guarantee that all the packages in a batch

63 — The Court took a similar view in its order in Case C-180/96 R *United Kingdom* v *Commission*, cited in footnote 52. It held that (paragraph 68): 'the reason for the containment measure's covering the whole of the United Kingdom rather than one or more specific regions is that the disease, while doubtless localized several years ago, had spread over the whole country, and that, since not all animals were adequately identified, it was impossible to determine where they came from or whether they had at any time in their life belonged to a herd in which cases of BSE had been found. In that regard, the United Kingdom stated at the hearing that only animals infected or suspected of being infected by BSE were recorded and it did not challenge the Commission's figure of 11 000 cases of animals affected by BSE whose herd of origin was not identifiable'. See also paragraph 75 of that order.

64 — As the Commission states, inspection at the production stage is the proper way to prevent these problems the world over. It is also the method used in the Codex Alimentarius of the Food and Agriculture Organization of the United Nations (FAO).

65 — The Annex to Directive 91/493 lays down conditions applicable to factory vessels, during and after landing, general conditions for establishments on land, special conditions for handling fishery products on shore, arrangements with regard to health control and monitoring of production conditions, and rules on the packaging, identification, storage and transport of the products concerned.

were free from pathogenic micro-organisms, even if the batch as a whole were found to comply with Community standards. [66] For that reason, inspection at the time of importation would be incomplete and also less representative and therefore less reliable than inspection at the production and processing stage.

95. In view of the foregoing considerations, there was no alternative solution and the Commission decision, adopted in accordance with the advice of the Standing Veterinary Committee, was the only measure which was appropriate and necessary for the protection of public health. [67]

(3) Balancing of advantages and disadvantages

96. According to Affish, the infringement of its freedom to pursue a trade, and the huge attendant damage which it would suffer as a consequence of the disappearance of the market for the Surimi product which accounts for 72% of its turnover, are disadvantages which are not offset by the advantages in terms of the protection of public health.

97. In the light of the foregoing analysis, it seems to me that, having regard to the higher interest of the objective pursued, namely the protection of public health, the disadvantages, namely the infringement of, in this case, Affish's freedom to pursue a trade [68] and the damage which it will suffer as a result of the prohibition on imports of the products concerned, regardless of the date on which those products were shipped from Japan, that is, before or after 7 April 1995 when Decision 95/119 was adopted, do not outweigh the advantages. There is therefore no doubt about the validity of the decision

66 — The importance attached to inspection at the production stage is also clear from Article 11(2) of Directive 91/493, under which fishery products imported from third countries must fulfil specific import conditions. Those conditions are fixed, *inter alia*, after inspection on the spot of the conditions of production, storage and dispatch of the fishery products for consignment to the Community.

67 — As the Finnish Government rightly points out in its observations, this power of the Commission is very important, particularly for the small countries of the Community, which do not have the resources needed in order to carry out the necessary veterinary checks.

68 — In *Germany* v *Council*, cited in footnote 51, paragraph 78, the Court recognized that the freedom to pursue a trade or business is one of the general principles of Community law, pointing out that that principle is not absolute, but must be viewed in relation to its social function. Consequently, the freedom to pursue a trade or profession may be made subject to restrictions, particularly in the context of a common organization of the market, provided that those restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute, with regard to the aim pursued, a disproportionate and intolerable interference impairing the very substance of the rights guaranteed; see also *Schräder*, cited in footnote 50, paragraph 15; Case 5/88 *Wachauf* [1989] ECR 2609, paragraph 18; and Case C-177/90 *Kühn* [1992] ECR I-35, paragraph 16.

from the point of view of infringement of the principle of proportionality. [69]

(D) *Infringement of the principle of equal treatment*

98. Affish is of the view that the Commission has infringed the principle of equal treatment of operators/importers of Surimi products from Japan, on the one hand, and from Thailand and Korea, on the other, a principle laid down in Article 40(3) of the Treaty. Surimi products from Japan compete with similar products from Thailand or Korea, which, although of inferior quality (in point of taste, composition and bacteriological hygiene), may be imported without restriction into the Community. According to Affish, the Commission should have sent its mission of experts to those countries as well, before adopting measures against Japanese kamaboko.

99. The Court has consistently held [70] that, under the second subparagraph of Article 40(3) of the Treaty, the common organization of the agricultural markets is to exclude any discrimination between producers or consumers within the Community and that 'prohibition of discrimination is only a specific expression of the general principle of equal treatment in Community law, which means that comparable situations are not to be treated differently and that different situations are not to be treated alike unless such treatment is objectively justified'.

100. In my opinion, the plaintiff's argument is unsubstantiated since Affish has not shown that the situation as regards conditions of production and marketing is the same in Korea and Thailand as it is in Japan, and that the Commission has therefore infringed the higher principle of equal treatment.

69 — In its order in Case C-180/96 R, cited in footnote 52, after balancing the conflicting interests, the Court dismissed the United Kingdom's application for suspension of the operation of Commission Decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy (OJ 1996 L 78, p. 47). To that end it stated (in paragraphs 91 to 93) that: 'It is true that the foregoing analysis has shown that damage to commercial and social interests is likely to result from maintaining the export ban in force for the time being and that a part of such damage would not easily be reparable if the main action were to be upheld. That damage cannot however outweigh the serious harm to public health which is liable to be caused by suspension of the contested decision, and which could not be remedied if the main action were subsequently dismissed'. It concluded as follows: 'Scientists have as yet only an imperfect knowledge of Creutzfeldt-Jakob disease and, more particularly, its recently-discovered variant. ... Since the most likely explanation of this fatal disease is exposure to BSE, there can be no hesitation. Whilst acknowledging the economic and social difficulties caused by the Commission's decision in the United Kingdom, the Court cannot but recognize the *paramount importance* to be accorded to the protection of health' (emphasis added).

70 — See, for example, Case C-311/90 *Hierl* [1992] ECR I-2061, paragraph 18; *Scholten-Honig*, cited in footnote 30, paragraphs 25 to 27; Case 203/86 *Spain* v *Council* [1988] ECR 4563, paragraph 10; Case 84/87 *Erpelding* [1988] ECR 2647, paragraph 29; Joined Cases C-267/88 to C-285/88 *Wuidart and Others* [1990] ECR I-435, paragraph 13; and Case C-63/93 *Fintan Duff* [1996] ECR I-569, paragraph 26.

(E) *Infringement of the principle of the protection of legitimate expectations*

101. Affish maintains that Article 19 of Directive 90/675 left some room for the principle of the protection of legitimate expectations to be taken into account but that the Commission disregarded that principle when it adopted the contested decision (95/119). It argues that the decision does not impose, and could not have imposed, an immediate ban on imports of fishery products originating in Japan and consequently an import ban on consignments which had already been shipped was not necessary since those consignments could have been subjected to a further inspection on arrival in the Community.

102. In its observations, the Italian Government argues in favour of the validity of the contested Commission decision and recognizes that in this case the Member States do not have the same wide margin of discretion as they have in implementing the measures necessary to comply with a Community directive, but points out that Decision 95/119, and in particular Article 3 thereof, does not expressly set a time-limit within which Member States must comply therewith. That points to the fact that it must be complied with within a strict and uniform time-limit consistent with the purpose of the act. The decision did not, however, preclude the national authorities, in adopting their implementing measures, from taking into account the special situation of consignments which had already been shipped, on the basis of the principle of legal certainty and the protection of legitimate expectations, and thereby fully safeguarding the Community interest.

103. According to the Rijksdienst, since the contested Commission decision did not set a transitional period or expressly provide for one to be set prior to its entry into force, the Netherlands Government was not entitled to lay down any such period. [71]

104. As the Court has repeatedly held: [72] 'That principle [the protection of legitimate expectations], which is part of the Community legal order, is the corollary of the principle of legal certainty, which requires that legal rules be clear and precise, and aims to ensure that situations and legal relationships governed by Community law remain foreseeable'. The Court continued: [73] 'It is settled case-law that in the sphere of the common organizations of the markets, whose purpose involves constant adjustments to meet changes in the economic situation, economic agents cannot legitimately expect that they will not be subject to restrictions arising out of future rules of market or structural policy'. The Court also pointed out that 'the principle of the protection of legitimate expectations may be invoked as against Community rules only to the extent that the Community itself has previously created a

71 — The contested Commission decision was published on 7 April 1995. The Netherlands Warenwetregeling, which was adopted in order to implement the decision in the Netherlands, is dated 13 April 1995 and entered into force on 15 April 1995.

72 — See *Fintan Duff*, cited in footnote 70, paragraph 20, and point 23 et seq. of my Opinion in that case. See also Joined Cases 205/82 to 215/82 *Deutsche Milchkontor* [1983] ECR 2633, paragraph 30, and *Kühn*, cited in footnote 68, paragraph 13.

73 — Judgment in *Fintan Duff*, cited in footnote 70, paragraph 20.

situation which can give rise to a legitimate expectation'. [74]

105. In view of the Court's consistent case-law, I consider Affish's allegation that the Commission has infringed the principle of the protection of legitimate expectations to be unfounded. The provision on the basis of which Decision 95/119 was adopted imposes an obligation to achieve a certain result, namely the protection of public health. From the time when the Commission found itself obliged, on account of the serious deficiencies identified by the mission of experts in the veterinary checks carried out, to declare the prohibition imposed by it immediately enforceable in order to protect public health, the Member States were obliged to comply with it.

106. It is precisely because the objective pursued by the decision was the protection of public health that it would, in my opinion, have been injudicious to leave the timing open in order to accommodate the legitimate expectations of the individuals affected. Consequently, it was of little relevance whether a few consignments were shipped from Japan before or after 7 April 1995.

107. I am therefore of the opinion that the possible fixing of a transitional period by the Member States would have jeopardized the uniform application of Community law and the effectiveness of the measure adopted. [75] If a Member State had fixed a transitional period for consignments already shipped, it would, in my view, have infringed Article 189 of the Treaty, pursuant to which a decision is binding in its entirety upon all those to whom it is addressed. [76]

108. On all those grounds, the absence of transitional measures cannot affect the validity of Commission Decision 95/119.

(F) *Breach of the Agreement on the application of sanitary and phytosanitary measures*

109. This argument put forward by Affish concerns the interpretation and direct effect of the Agreement on the application of sanitary and phytosanitary measures. [77] Affish claims that, by its decision, the Commission has breached the Agreement, the provisions of which, according to Affish, may be relied on by undertakings and private individuals

74 — See, for example, *Kühn*, cited in footnote 68, paragraph 14.

75 — See Case 112/80 *Dürbeck* [1981] ECR 1095 which concerned the temporary suspension of the release into free circulation in the Community of apples from Chile, in which the Court held as follows (paragraph 50): 'in view of the needs which the temporary suspension of imports met, transitional measures which exempted contracts already entered into from the suspension of imports would have robbed the protective measure of all practical effect by opening up the Community market in dessert apples to a volume of imports likely to jeopardize that market'.

76 — Article 191(3) of the Treaty provides, moreover, that decisions are to be notified to those to whom they are addressed and are to take effect upon such notification.

77 — Already cited in footnote 3.

before the national courts since they contain clearly worded obligations which are capable of judicial review. In the proceedings before the national court, it argued that, even if the Agreement does not have direct effect, Community law, and in particular Article 19 of Directive 90/675, must be interpreted in the light of the Agreement.

(1) Admissibility

110. The agent of the Netherlands Government pointed out at the hearing that the national court is not asking the Court directly whether Decision 95/119 is invalid on account of breach of the Agreement, although the national court mentions in its order for reference that Affish did indeed raise that question. That is why, according to the Netherlands Government, the examination by the Court of this aspect of the case raises the question of admissibility. It is precisely because the national court has not raised the question that the Member States have not made known their point of view on the matter in accordance with Article 20 of the Protocol on the Statute of the Court of Justice of the European Community. [78]

78 — The Court has consistently held that the order for reference must contain the necessary information on the factual and legislative context of the case in order to enable the Member States and other interested parties to submit observations pursuant to Article 20 of the Statute of the Court; see, for example, the orders in Case C-2/96 *Sunino* [1996] ECR I-1543, paragraph 5, and Case C-458/93 *Saddik* [1995] ECR I-511, paragraph 12; and the judgment in Joined Cases 141/81 to 143/81 *Holdijk and Others* [1982] ECR 1299, paragraph 6.

111. I am of the opinion that the foregoing line of argument cannot be accepted. Since the order for reference from the national court mentions this point, in that Affish raised it in its observations before that court, it is necessary, in order to provide the national court with a helpful answer, to examine this point so as to remove any doubt concerning the validity of the contested decision. [79]

(2) The direct effect of the provisions of the Agreement

112. As the Court has consistently held, in considering whether the provisions of an international agreement concluded by the Community can have direct effect, it is necessary, after first examining the spirit, wording and scheme of the agreement, to examine to what extent the individual is entitled to rely on those provisions before the national courts. In other words, it is necessary to ascertain whether they are sufficiently precise and unconditional or require the adoption of

79 — The Court's case-law does not preclude examination of a plea relied on by a party even though the national court does not expressly refer to it; see *Scholten-Honig*, cited in footnote 30, paragraphs 16 and 17. Moreover, the Court has, on a number of occasions, interpreted provisions even though the national court did not expressly request their interpretation, and assessed to what extent provisions whose validity the national court had called in question were in accordance with provisions which the Court was interpreting on its own initiative; however, this was always done in order to provide the national court with a helpful answer to the questions referred for a preliminary ruling; see, for example, *Simmenthal*, paragraph 57; *Claeys*, paragraphs 21 and 10; and *Viessmann*, paragraph 17, all cited in footnote 32.

more detailed implementing measures. In my opinion, this question must be examined in the context of the set of agreements reached in the Uruguay Round multilateral negotiations (1986-1994). [80]

113. Under the General Agreement on Tariffs and Trade (GATT) which was in force at the time, the Court, when examining the spirit, scheme or wording of that Agreement, consistently held [81] that, because of its special features, 'an individual may not invoke it in a court to challenge the lawfulness of a Community act' and that those features also preclude 'the Court from taking provisions of GATT into consideration to assess the lawfulness of a regulation in an action brought by a Member State under the first paragraph of Article 173 of the Treaty'. [82]

114. Next, I shall examine to what extent we can conclude from its spirit, scheme and wording whether it is possible to rely directly on the provisions of the recent Agreement Establishing the World Trade Organization, [83] to which the Agreement now under consideration is an annex, in order to contest before a court the lawfulness of a Community act, having regard to the primacy of international agreements concluded by the Community over provisions of secondary Community legislation. [84] An analysis of the Agreement in the light of both its object and purpose and of its provisions as a whole may help us to answer the question whether or not it has direct effect.

115. The Court has consistently pointed out that the effect of an international agreement in the Community legal order must be determined having regard to the objectives and nature of that agreement. The Court has also made it clear that the said effect cannot be ascertained without taking into account the international origin of the provisions of the agreement in question and that, in conformity with the principles of public international law, the contracting parties are free to agree what effect the provisions of the agreement are to have in their respective internal legal orders. [85]

116. In its examination of the spirit, scheme and wording of the GATT 1947, the Court held that that agreement which, according to its preamble, is based on the principle of negotiations undertaken 'on the basis of reciprocal and mutually advantageous arrangements', 'is characterized by the great flexibility of its provisions, in particular those conferring the possibility of derogation, the measures to be taken when confronted with exceptional difficulties and the

80 — This was acknowledged by the Court, for example, during its examination of the results of the Agreement on free trade between the Community and Portugal in Case 104/81 *Kupferberg* [1982] ECR 3641, paragraph 23. See also *Germany* v *Council*, cited in footnote 51, paragraphs 105 to 110; Joined Cases 21/72 to 24/72 *International Fruit Company* [1972] ECR 1219, paragraphs 19 to 29; and Case 266/81 *SIOT* [1983] ECR 731, paragraph 28.

81 — See *Germany* v *Council*, cited in footnote 51, paragraph 109. See also the earlier judgments in Joined Cases 21/71 to 24/72 *International Fruit Company*, cited in footnote 80, paragraphs 19 to 29; Case 9/73 *Schlüter* [1973] ECR 1135, paragraphs 28 to 30; and *SIOT*, cited in footnote 80, paragraph 28.

82 — In addition, see Case C-469/93 *Chiquita Italia* [1995] ECR I-4533, paragraphs 26 to 29.

83 — Already cited in footnote 4.

84 — See Case C-61/94 *Commission* v *Germany* [1996] ECR I-3989, paragraph 52.

85 — *Kupferberg*, cited in footnote 80, paragraph 17.

settlement of conflicts between the contracting parties'. [86] The Court analyzed in turn the features of the former GATT and found that 'the GATT rules are not unconditional and that an obligation to recognize them as rules of international law which are directly applicable in the domestic legal systems of the contracting parties cannot be based on the spirit, general scheme or terms of GATT'. [87]

117. The Court found that no obligation could be inferred from the GATT rules for the contracting parties to recognize those rules as rules of international law directly applicable within their national legal systems. [88] In the absence of such an obligation following from GATT itself, the Court left open the possibility that it could 'review the lawfulness of the Community act in question from the point of view of the GATT rules ... only if the Community intended to implement a particular obligation entered into within the framework of GATT, or if the Community act expressly refers to specific provisions of GATT'. [89]

118. I shall examine whether the provisions in question, both of the Agreement Establishing the World Trade Organization and of the new General Agreement, [90] are capable of producing direct effect in accordance with the criteria set out by the Court and, more particularly, whether individuals can be regarded as entitled to rely directly on the provisions of the Agreement.

119. I am of the opinion that the provisions of both the WTO Agreement and GATT 1994 are still characterized by great flexibility, which means that they cannot be regarded as having direct effect and that an individual is not entitled to rely on them before the national courts. [91] This applies with respect to the possibility of derogation and the measures to be taken when confronted with exceptional difficulties as well

86 — See, in particular, *International Fruit Company*, cited in footnote 80, paragraph 21, and *Germany* v *Council*, cited in footnote 51, paragraph 106.

87 — See, in particular, *Germany* v *Council*, cited in footnote 51, paragraph 110.

88 — *Germany* v *Council*, cited in footnote 51, paragraph 110.

89 — See *Germany* v *Council*, cited in footnote 51, paragraph 111, and the earlier judgments in Case 70/87 *Fediol* [1989] ECR 1781 and Case C-69/89 *Nakajima* [1991] ECR I-2069.

90 — OJ 1994 L 336, p. 11.

91 — For more general background on these issues, see, for example, the articles by Paolo Mengozzi, 'Les droits des citoyens de l'Union européenne et l'applicabilité directe des accords de Marrakech' in *Revue du Marché Unique Européen*, 1994, part 4, pp. 165 to 174, and C. W. A. Timmermans, 'L'Uruguay Round: sa mise en oeuvre par la Communauté européenne', in *Revue du Marché Unique Européen*, 1994, part 4, pp. 175 to 193.

as to the provisions on the settlement of disputes between the contracting parties. [92]

120. The Agreement is aimed at the application of sanitary and phytosanitary measures and its provisions must undoubtedly be interpreted in the light of all the rules resulting from GATT 1994. More particularly, with regard to Articles 2 and 5, I am of the opinion that they are not so clearly and specifically worded that the individual may rely on them before the national courts. [93] As is

92 — It is true that the new GATT 1994 contains a new system for the settlement of disputes between Members along the lines of the judicial model, which offers more certainty in the sphere of application of the recommendations and decisions of the Dispute Settlement Body (hereinafter: 'DSB'), unlike the old GATT. That system is set out in Annex 2 to the WTO Agreement, which incorporates the Understanding on Rules and Procedures governing the Settlement of Disputes (OJ 1994 L 336, p. 234). However, the spirit of negotiations, which characterized the old GATT, is not altogether absent from the new GATT.
Thus, the possibility of compensation or the suspension of concessions or other obligations continues to be available to Members (Article 22(1) of the Understanding) for the settlement or prevention of disputes.
Furthermore, the quasi-judicial character of the DSB is diminished by the fact that Article IX of the WTO Agreement, headed 'Decision-Making', provides, notwithstanding the practice of decision-making by consensus introduced by GATT 1947 (paragraph 1), that the Ministerial Conference and the General Council composed of representatives of all the Members, that is, political (intergovernmental) bodies, are to have exclusive authority to adopt interpretations of the Agreement and of the Multilateral Trade Agreements (paragraph 2).
Moreover, the possibility for any Member to modify or withdraw its commitments is maintained (Article XXI of the General Agreement on Trade in Services (GATTS), incorporated as Annex 1B to the WTO Agreement) (OJ 1994 L 336, p. 190)). That spirit of flexibility is also exemplified by Article XX of the Agreement, under which each Member may set out in a schedule the specific commitments which it undertakes with regard to market access for services and service suppliers of another Member.
The new GATT provides that, in the event of a dispute in which the procedure for dispute settlement laid down in the Understanding is followed, the Members may conclude agreements on mutually acceptable compensation (Article 22(2) and (3) of the Understanding).
Article 8(2) of the Agreement on Safeguards (which forms part of Annex 1A to the WTO Agreement, OJ 1994 L 336, p. 184) rather limits the scope which a Member has for adopting safeguard measures in order to prevent very large volumes of imports or the risk of serious injury to its domestic industry from like or indirectly competitive products (Article 2), but allows the adoption of such measures (while offering adequate compensation for the adverse effects of the measure on the trade of the Members concerned), in particular, reduction of the obligations resulting from GATT 1994 (Article 8; see also Article 5). More specifically, there is provision for suspending the application of concessions or other obligations of a similar nature resulting from GATT 1994 to the trade of the Member applying the safeguard measure. Likewise, the possibility of adopting provisional measures in exceptional circumstances is maintained (Article 6). The application of safeguard measures is allowed for however long is necessary in order to prevent the risk of serious damage or to eliminate adverse consequences or facilitate adjustment (Article 7), and in no case longer than 8 years (Article 7(3)), but that does not alter the flexible character of GATT 1994.
See also the reservations expressed by C. W. A. Timmermans on this point in his article cited in footnote 91, p. 178 et seq.

93 — In Case 87/75 *Bresciani* [1976] ECR 129, paragraph 25, the Court held that Article 2(1) of the Convention of Association between the European Economic Community and the African States and Madagascar associated with the Community, signed at Yaoundé on 20 July 1963, which expressly refers to Article 13 of the EEC Treaty, has direct effect, and therefore confers, with effect from 1 January 1970, on those subject to Community law the right, which the national courts must protect, not to pay to a Member State a charge having equivalent effect to customs duties, 'since this obligation is specific and not subject to any implied or express reservation on the part of the Community'.
In Case 17/81 *Pabst* [1982] ECR 1331, which concerned the Agreement establishing an Association between the EEC and Greece, signed in Athens on 9 July 1961 and approved and confirmed on behalf of the Community by decision of the Council of 25 September 1961 (OJ, English Special Edition, Second Series, I External Relations (1), p. 3), the Court held (in paragraph 27) that it follows from the wording of Article 53(1) and from the objective and nature of the Association Agreement that 'that provision ... contains a clear and precise obligation which is not subject, in its implementation or effects, to the adoption of any subsequent measures. In those circumstances, Article 53(1) must be considered as directly applicable ...'. Accordingly, the Court concluded (paragraph 28), an importer of spirits from other Member States or from Greece was entitled to rely before a national court on, *inter alia*, Article 53(1) of the Association Agreement with Greece.
Case C-18/90 *Kziber* [1991] ECR I-199 concerned the question of the extent to which the Cooperation Agreement between the European Economic Community and the Kingdom of Morocco, signed in Rabat on 27 April 1976 and concluded on behalf of the Community by Council Regulation (EEC) No 2211/78 of 26 September 1978 (OJ 1978 L 264, p. 1), has direct effect. After first examining the terms of the Agreement (paragraph 16), the Court held that Article *41*(1) was capable of being applied directly (paragraph 23) and could be relied on before the national court, regard being had, on the one hand, to the nature and purpose of the Agreement, and on the other, to the meaning of the provision, which defined the persons entitled to certain benefits and their rights sufficiently precisely and thus had direct effect (paragraphs 24 to 29).

clear from the terms of the Agreement, most of the provisions of the contested articles (2 and 5) are addressed to the Members of the World Trade Organization [94] and although they contain obligations to act or to refrain from acting, [95] they also require supplementary implementing measures, that is, more detailed implementing provisions to be adopted, [96] as the Court has pointed out in similar cases in which it has reviewed the direct effect of international agreements. [97]

121. The need for more detailed implementing measures becomes apparent on examination of a series of provisions of the Agreement. For example, Article 2(2) of the Agreement provides that a sanitary or phytosanitary measure may not be maintained without 'sufficient scientific evidence'. It is for the competent authorities to determine what constitutes 'sufficient' scientific evidence. [98]

122. The express references to 'scientific evidence' (Article 5(2) and (3) of the Agreement) and 'relevant economic factors' (Article 5(3)) cannot, in my opinion, create any direct obligations for Members. Further, the adoption of more detailed implementing

94 — The wording used is clear: 'Members shall ensure' (Article 2(2) and (3)), 'Members shall take into account' (Article 5(2), (4) and (6)), 'a Member may provisionally adopt sanitary or phytosanitary measures', and 'Members shall seek to obtain' (Article 5(7)).

95 — We read: 'Members shall ensure', 'Members shall take into account': in my opinion, the verb form here must be construed as having mandatory force.

96 — In Case C-277/94 *Taflan-Met* [1996] ECR I-4085, the Court did not deny that Decision No 3/80 of the Association Council of 19 September 1980 on the application of the social security schemes of the Member States of the European Communities to Turkish workers and members of their families (OJ 1983 C 110, p. 60) is binding on the Contracting Parties, but answered the question referred for a preliminary ruling as follows: 'So long as the supplementary measures essential for implementing Decision No 3/80 have not been adopted by the Council, Articles 12 and 13 of that decision do not have direct effect in the territory of the Member States and are therefore not such as to entitle individuals to rely on them before the national courts'. See also the earlier judgments in *Kziber*, cited in footnote 93, paragraph 15, and Case 12/86 *Demirel* [1987] ECR 3719, paragraph 14.

97 — It can be inferred from the Court's case-law that, until the Community has adopted the necessary implementing measures for the purpose of fulfilling its obligations under GATT, it cannot be compelled to do so by judicial means by the operators concerned. In such circumstances, it will be entitled to use the remedies made available by GATT 1947 and negotiate a solution with the affected third Member. However, if the Commission has fulfilled its obligation, it has deprived itself of that possibility, and the parties concerned are entitled to rely on the provision concerned before the courts. For example, in Case 70/87 *Fediol*, cited in footnote 89, the Court held (paragraph 20) that the flexibility which is a feature of the provisions of GATT 'does not, however, prevent the Court from interpreting and applying the rules of GATT with reference to a given case, in order to establish whether certain specific commercial practices should be considered incompatible with those rules. The GATT provisions have an independent meaning which, for the purposes of their application in specific cases, is to be determined by way of interpretation.' That conclusion, reached by the Commission, can again be found in Council Regulation (EEC) No 2641/84 of 17 September 1984 on the strengthening of the common commercial policy with regard in particular to protection against illicit commercial practices (OJ 1984 L 252, p. 1), which was at issue in that case: that regulation confers on the operators concerned the right to rely, in their complaint lodged with the Commission, on the provisions of GATT in order to have it established whether the practices by which they claim to have been injured are unlawful.
In Case C-69/89 *Nakajima* v *Council*, cited in footnote 89, which concerned the applicability of Council Regulation (EEC) No 2423/88 of 11 July 1988 on protection against dumped or subsidized imports from countries not members of the European Economic Community (OJ 1988 L 209, p. 1), the Court ruled that the possibility of questioning the validity of the regulation for breach of the Anti-Dumping Code adopted in 1979 within the framework of GATT for the purpose of implementing Article VI thereof does not presuppose that the Agreement in question has direct effect. That possibility exists because GATT is binding on the Community and the contested regulation was adopted in order to comply with the international obligations of the Community (see paragraphs 28 to 31).
The Court also followed that approach in *Germany* v *Council*, cited in footnote 51, paragraph 111).

98 — The Commission observes that there is disagreement between the Community and its commercial partners on the question whether there is 'sufficient' scientific evidence in order to prohibit the use of hormones in cattle-breeding, and the question has now been referred to a special group of the WTO in Geneva.

measures is therefore necessary. The same problem arises with regard to Article 5(4) which provides that, when determining their appropriate level of sanitary or phytosanitary protection, 'Members should ... take into account the objective of minimizing negative trade effects'.

123. The need for implementing measures is also apparent from Article 5(6) and (7). Paragraph 6 refers to measures which Members adopt with a view to achieving the 'appropriate level' of sanitary or phytosanitary protection, provided that such measures are not more trade-restrictive than required to achieve that level, taking into account technical and economic feasibility. Finally, paragraph 7, pursuant to which, in the absence of scientific evidence, the competent national authority may provisionally adopt sanitary or phytosanitary measures, likewise makes it clear that the definition of such evidence requires the adoption of further implementing measures.

124. Any assumption that all the provisions of the Agreement are unconditional is refuted by the fact that the least-developed countries may delay application of its provisions for a period of five years following the date of entry into force of the WTO Agreement, while other developing countries may delay application for two years (Article 14). At the same time, there is provision for special and differential treatment for those countries' products (Article 10).

125. Article 13 provides that Members are fully responsible for the observance of all obligations set forth in the Agreement. However, that may be assumed to refer to the international responsibility of Members, irrespective of which body (governed by public or private law) is entrusted with the enforcement of rules concerning sanitary or phytosanitary protection. [99]

126. It may be inferred from Article 14 of the Agreement on Agriculture, [100] headed 'Sanitary and Phytosanitary Measures', [101] that the Members considered further imple-

99 — This is clear from Article XXIV: 12 as interpreted by the Understanding on the Interpretation of Article XXIV of the General Agreement on Tariffs and Trade 1994 (OJ 1994 L 336, p. 16), which reads as follows:
'Each Member is fully responsible under GATT 1994 for the observance of all provisions of GATT 1994, and shall take such reasonable measures as may be available to it to ensure such observance by regional and local governments and authorities within its territory.'

100 — OJ 1994 L 336, p. 22.

101 — Article 14 reads as follows:
'Members agree to give effect to the Agreement on the application of sanitary and phytosanitary measures'.

menting measures to be necessary for the entry into force of the Agreement. [102]

127. Finally, I am of the opinion that the 11th recital in the preamble to Council Decision 94/800 approving the agreements reached in the Uruguay Round multilateral negotiations, which states that 'by its nature, the Agreement establishing the World Trade Organization, including the Annexes thereto, is not susceptible to being directly invoked in Community or Member State courts', must be read in the light of the foregoing analysis. In the absence of a corresponding provision in the text of Decision 94/800, that recital cannot by itself preclude the direct effect of the provisions of the Agreement. That is why an analysis of the wording, scheme and spirit of the Agreement and, in general, of the agreements reached in the Uruguay Round multilateral negotiations, was necessary. The existence of that recital [103] merely reflects the fact that the weighty reasons which led the Court to hold that no direct effect could be conferred on GATT 1947 [104] have not ceased to apply with the conclusion of GATT 1994 and the WTO Agreement, as the Commission has also pointed out. [105]

128. I therefore conclude that while the Agreement has certainly introduced a new system which is binding on its members, it does not have direct effect, that is to say, the provisions of the Agreement may not be invoked by individuals before the national courts.

(3) The incompatibility of Decision 95/119 with Articles 2 and 5 of the Agreement

129. Although I have concluded that the provisions of the Agreement do not have direct effect and that individuals may not

102 — Under the fourth recital in the preamble to the Agreement on Agriculture, cited in footnote 100, the Members are 'committed ... to reaching an agreement on sanitary and phytosanitary issues'.

103 — See the severe criticism levelled at the insertion of that recital in the preamble to Decision 94/800 by Professor Paolo Mengozzi in his article cited in footnote 91 (p. 168 et seq.). Mengozzi is also an advocate of direct effect for the provisions of the new GATT, because otherwise the primacy of Community law in the national legal systems could be jeopardized (p. 174).

104 — See, for example, *Germany* v *Council*, cited in footnote 51, paragraphs 106 to 108.

105 — Moreover, in explaining the inclusion of this recital in the preamble to Decision 94/800, the Commission states that other contracting parties (the United States and Canada) were of the opinion that GATT 1994 does not have direct effect. In its view, that is also why, in the absence of reciprocity, GATT cannot have direct effect in the Community. I consider that argument to be irrelevant for the purpose of answering the question whether or not the Agreement has direct effect, because the Commission does nor substantiate its assertion and because, as the Court has stated: 'According to the general rules of international law there must be *bona fide* performance of every agreement. Although each contracting party is responsible for executing fully the commitments which it has undertaken, it is nevertheless free to determine the legal means appropriate for attaining that end in its legal system unless the agreement, interpreted in the light of its subject-matter and purpose, itself specifies those means. Subject to that reservation, the fact that the courts of one of the parties consider that certain of the stipulations in the agreement are of direct application whereas the courts of the other party perhaps do not recognize such direct application is not in itself such as to constitute a lack of reciprocity in the implementation of the agreement'; see *Kupferberg*, cited in footnote 80, paragraph 18.

rely on them before the national courts, nevertheless, should the Court rule otherwise, and having regard to the Court's settled case-law under which the primacy of international agreements concluded by the Community over secondary Community legislation means that such legislation 'must, so far as is possible, be interpreted in a manner that is consistent with those agreements', [106] I shall for the sake of completeness examine to what extent the Commission decision is contrary to Articles 2 and 5 of the Agreement.

130. First, Affish maintains that, by basing its decision solely on the experts' report without having regard to other available information, such as, for example, inspection reports on products which had already been imported into the Community over a long period of time, or earlier inspections of factories from where Affish obtains its products, which showed no evidence of any danger to public health, the Commission acted in breach of Article 5(7) of the Agreement.

131. Second, according to Affish, the Commission acted in breach of Article 2(3) of the Agreement since the measure adopted by it results in arbitrary or unjustified discrimination between Members where identical or similar conditions prevail, as well as between their own territory and that of other Members, and has been applied in such a way as to constitute a disguised restriction on international trade.

132. Affish further maintains that the Commission did not comply with the obligations resulting from Article 5(4) and (6) of the Agreement, namely to minimize the negative effects on trade of such measures adopted and to ensure that such measures were not more trade-restrictive than required to achieve an appropriate level of sanitary or phytosanitary protection.

133. In my view, those arguments put forward by Affish cannot be accepted since they are not supported by any evidence.

134. The sixth recital in the preamble to the Agreement refers to the guidelines and recommendations developed by the Codex Alimentarius Commission as the basis for any sanitary and phytosanitary measures adopted by Members. That is also stipulated by Article 3(1) of the Agreement. As the Commission contends, its action is based on and is in conformity with internationally

106 — See *Commission* v *Germany*, cited in footnote 84, paragraph 52. In Case C-70/94 *Werner* [1995] ECR I-3189, paragraph 23, and Case C-83/94 *Leifer* [1995] ECR I-3231, paragraphs 23 and 24, the Court interpreted Council Regulation (EEC) No 2603/69 of 20 December 1969 establishing common rules for exports (OJ, English Special Edition (II), p. 590) in the light of the provisions of Article XI of GATT 'which can be considered to be relevant for the purposes of interpreting a Community instrument governing international trade'.

accepted principles and procedures which are not inconsistent with the Agreement. [107]

135. Under Article 5(2) of the Agreement, in assessing risks, Members are to take into account, among other factors, relevant production processes and production methods.

136. The Commission points out that the provisions of Directive 91/493 are based on findings and principles set out by the Codex Alimentarius Commission and are in accordance with the latter's recommendations, and that emphasis has rightly been laid, in particular, on veterinary checks at the production stage, that is, the stage between the catching and packaging of the fish.

137. Since the mission of experts drew attention in its report (point 3) to the inadequacy of the checks carried out by the Japanese authorities at the establishments visited and to the serious public health risks resulting from the conditions of production and packaging of the products concerned, in my view the Commission was lawfully entitled, in accordance with Article 2(1) of the Agreement, to adopt the contested decision.

138. In the light of the foregoing analysis, and in particular of the possible infringement of the principle of proportionality, the measure adopted clearly cannot, since it was directed towards the protection of public health, be claimed to be 'more trade-restrictive than required to achieve an appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility', as stated in Article 5(6) and the explanatory footnote thereto.

139. To recapitulate, let me reiterate that, under the Community legislation in force, the Commission is required to act on the basis of uniform rules with regard to the determination of the health conditions which fishery products, whether or not of Community origin, must satisfy; that seems to me to be shown by the principle of equivalence contained in Article 10 of Directive 91/493. Since, moreover, the Commission took as the basis for its decision reliable information supplied by experts, I am of the opinion that Affish's allegation that the Commission drew an 'arbitrary and unjustified distinction between Members where identical or similar conditions prevail' and that the measure adopted by it constitutes a 'disguised restriction on international trade' within the mean-

107 — The Commission states that the Codex Alimentarius Commission publishes internationally recommended codes of practice, in particular in the field of fishery products. The two most important principles in that commission's recommendations are the identification of possible public health risks arising at the production stage, and the control of critical points in the production process.

ing of Article 2(3) of the Agreement must be rejected for lack of evidence. [108]

(G) *Misuse of powers and abuse of process*

(1) Misuse of powers

140. The national court and Affish raise the question whether the Commission used its powers under Article 19 of Directive 90/675 as a means of bringing pressure to bear on third countries in order to induce the health authorities in those countries to tighten up their supervision. In other words, were those powers used, not for the protection of the health of the consumer, but as an instrument of commercial policy, in order to bring about the adoption in Japan of a harmonized system of controls for fish-processing establishments, equivalent to the system which exists in the Community?

141. The question which thus arises in substance is whether the contested Commission decision is invalid on account of misuse of powers, that is, whether it was adopted for a purpose other than that for which Article 19 conferred the relevant power on the Commission.

142. Affish has not produced the evidence required to substantiate an allegation of misuse of powers and for the Commission's decision to appear, 'on the basis of objective, relevant and consistent indications', to have been adopted for purposes other than those for which it was intended. [109]

143. Moreover, the facts, as set out in the experts' report and in the first recital in the preamble to the decision, viewed as a whole, show that there were serious grounds for adopting measures for the protection of public health, since serious defects as regards hygiene and control had been identified at the fish-processing establishments visited. That is why, in adopting its decision, the Commission had regard above all to protecting public health, as it is obliged to do pursuant to Directive 90/675. [110]

144. The Commission therefore did not use the powers vested in it by Article 19 for a purpose other than that for which they were conferred, since it manifestly had in view the protection of public health. There was thus no misuse of powers.

108 — The Commission points out that Japan has not raised the question whether Decision 95/119 is in conformity with the Agreement. Following the negative findings of the mission of experts and the adoption of the decision by the Commission, the Japanese authorities even suspended the issue of health certificates from the beginning of May 1995. On 7 August 1995, they sent to the Commission a new list of two approved establishments. On 7 September 1995, they announced that four further establishments had been approved. Thereafter, the issuing of health certificates was resumed only for products from those establishments.

109 — See, for example, Case C-323/88 *Sermes* [1990] ECR I-3027, paragraph 33, and *Nakajima*, cited in footnote 89, paragraph 134.

110 — See the Court's reasoning by analogy in *Commission* v *United Kingdom*, cited in footnote 52, paragraph 62.

(2) Abuse of process

145. Affish maintains that, in sending a mission of experts to Japan, the Commission followed the procedure under Article 11 of Directive 91/943 with a view to adopting the contested act. However, according to Affish, the procedure in question is intended to allow specific import conditions to be fixed and should not have been used as the basis for an import prohibition under Article 19 of Directive 90/675. Hence the question arises whether there has been an abuse of process on grounds which could lead the Court to declare Decision 95/119 void.

146. As a ground for annulment of a measure adopted by a Community institution, 'abuse of process' constitutes a special subcategory within the wider concept of 'misuse of powers'. [111] It implies that, by circumventing the relevant provisions laying down the procedure to be followed in taking a decision, the institution in question has adopted the measure by following another procedure, prescribed for a different purpose. [112]

147. Affish's argument cannot be accepted. Within the scope of its powers under Article 19 of Directive 90/675, the Commission may assess whether a serious animal health or public health reason requires it to act, and to that end it was entitled to take into account the disturbing conclusions of the experts sent out by it.

VI — Conclusion

148. In view of the foregoing considerations, I propose that the Court should answer the question referred to it by the College van Beroep voor het Bedrijfsleven for a preliminary ruling as follows:

Consideration of the question raised has disclosed no factor of such a kind as to affect the validity of Commission Decision 95/119/EC of 7 April 1995 concerning certain protective measures with regard to fishery products originating in Japan.

111 — See, in particular, Case 2/57 *Compagnie des Hauts Fourneaux de Chasse* [1958] ECR 199 and Joined Cases 32/87, 52/87 and 57/87 *ISA* [1988] ECR 3305, paragraph 19. In Case C-225/91 *Matra* [1993] ECR I-3203, paragraph 25, the Court expressly states that it also examines whether there has been an abuse of process.

112 — See *Fedesa*, cited in footnote 45, paragraph 24, and points 68 to 70 of my Opinion in Case C-122/94 *Commission* v *Council*, cited in footnote 39.