



JUDGMENT OF THE COURT

14 July 2000*

(Free movement of goods – Directives on dangerous substances and preparations – Joint Statements of the EEA Joint Committee)

In Case E-2/00

REQUEST to the Court under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by Oslo byrett (Oslo City Court) for an Advisory Opinion in the case pending before it between

Allied Colloids and Others

and

The Government of Norway, represented by the Ministry of Local Government and Regional Development

on the interpretation of the Agreement on the European Economic Area (hereinafter variously “EEA” and “EEA Agreement”), with particular reference to the following Acts:

- the Act referred to in Point 1 of Annex II, Chapter XV (Council Directive 67/548/EEC of 27 June 1967, on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as amended, hereinafter the “Substances Directive”);

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Language of the Request for an Advisory Opinion: Norwegian.

- the Act referred to in Point 10 of Annex II, Chapter XV (Council Directive 88/379/EEC of 7 June 1988, on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, as amended, hereinafter the “Preparations Directive”);

(hereinafter collectively the “Directives”);

- Joint Statement by the EEA Joint Committee adopted on 22 June 1995, concerning the EEA Agreement – Annex II, Chapter XV – regarding the review clauses in the field of dangerous substances (OJ 1996 C 6, p. 7, 11.1.96), in particular Annex II to that Joint Statement, setting up certain derogations concerning Norway, hereinafter the “Joint Statement of 1995”;
- Joint Statement by the EEA Joint Committee adopted on 26 March 1999, concerning the EEA Agreement – Annex II, Chapter XV – regarding the review clauses in the field of dangerous substances (OJ 1999 C 185, p. 6, 1.7.1999), in particular the Annex to that Joint Statement, setting up certain derogations concerning Norway, hereinafter the “Joint Statement of 1999”;

THE COURT,

composed of: Thór Vilhjálmsson (Judge-Rapporteur), President, Carl Baudenbacher and Per Tresselt, Judges,

Registrar: Gunnar Selvik,

after considering the written observations submitted on behalf of:

- the Plaintiffs, Allied Colloids and Others, represented by Counsel Wilhelm Matheson, Wiersholm, Mellbye & Bech;
- the Defendant, The Government of Norway, represented by the Ministry of Local Government and Regional Development, represented by Counsel

Hanne Bjurstrøm and Counsel Morten Goller, Office of the Attorney General (Civil Affairs);

- the Government of Iceland, represented by Högni S. Kristjánsson, Legal Officer, Ministry of Foreign Affairs, acting as Agent;
- the EFTA Surveillance Authority, represented by Anne-Lise H. Rolland, Officer, Legal & Executive Affairs, acting as Agent;
- the Commission of the European Communities, represented by Richard B. Wainwright, Principal Legal Adviser and Lena Ström, Legal Adviser, Legal Service, acting as Agents;

having regard to the Report for the Hearing,

after hearing the oral observations of the Plaintiffs, the Defendant, the Government of Iceland, the EFTA Surveillance Authority and the Commission of the European Communities, represented by Michael Shotter, Legal Adviser, Legal Service, acting as Agent, at the hearing on 22 June 2000,

gives the following

Judgment

Facts and procedure

- 1 By a reference dated 22 February 2000, registered at the Court on 25 February 2000, Oslo byrett made a Request for an Advisory Opinion in a case pending before it between Allied Colloids and Others (hereinafter the “Plaintiffs”) and the Government of Norway, represented by the Ministry of Local Government and Regional Government (hereinafter the “Defendant”). The dispute before the national court concerns the issue of whether the EEA Agreement allows the Defendant to require the Plaintiffs to label polyacrylamide as carcinogenic when the content of the residual substance acrylamide is equal to or greater than 0.01% by volume.
- 2 The Plaintiffs Allied Colloids, BASF Aktiengesellschaft, CYTEC Industries B.V., Nalco Chemical B.V., SNF Floerger and Betz Dearborn Europe NV are

manufacturers of polyacrylamide, whilst the Plaintiffs Nalco Norge AS, Paus & Paus AS, Norsk Hydro and Dyno Oil Field Chemicals are importers and distributors of polyacrylamide.

- 3 The Ministry of Local Government and Regional Development is responsible for the Directorate of Labour Inspection (hereinafter the “Labour Inspection”), which administers Chapter XIII of the Act relating to Worker Protection and Working Environment (Act No. 4 of 4 February 1977 relating to Worker Protection and Working Environment, hereinafter the “Working Environment Act”). The Labour Inspection adopts *inter alia* administrative regulations and decisions concerning the classification, labelling, etc. of dangerous chemicals under regulations adopted pursuant to *inter alia* Section 18(3) and Section 74(1), third paragraph of the Working Environment Act.
- 4 On 9 April 1997, the Labour Inspection ordered the importers of polyacrylamide to classify and label polyacrylamide products containing 0.01% or more by volume of the chemical substance acrylamide with a poison symbol and a text stating that the product may cause cancer. The deadline for compliance was 1 June 1997. This order was contested by the Plaintiffs in a letter of 21 May 1997, in which they requested permission for deferral of compliance with the labelling order. The Labour Inspection granted permission for deferral of compliance by an order of 27 May 1997. On 19 August 1998, the Ministry of Local Government and Regional Development upheld the order of the Labour Inspection.
- 5 Subsequently, the Plaintiffs brought an action in Oslo byrett, requesting that the order of the Ministry of Local Government and Regional Development be declared null and void, on the grounds that the order was contrary to EEA law. Contemporaneously, the Plaintiffs applied for an injunction to defer compliance with the order until such time as a final judgment had been rendered in the main proceedings. On 30 November 1998, Oslo byrett issued an interlocutory order rejecting the application on the grounds that it had not been demonstrated that the order was in breach of EEA law. The Plaintiffs appealed the interlocutory order to Borgarting lagmannsrett (Borgarting Court of Appeal), which affirmed the lower court’s decision by an order dated 25 March 1999. However, the appeal court did not deal with the issue of EEA law in the case. It found that there was no danger of irreparable harm and that, therefore, it was not necessary to decide the question of law. This second order was not appealed.

- 6 While the above proceedings have run their course, the Labour Inspection has re-issued its labelling order, first with a compliance deadline of 18 May 1999 and later with a deadline of 1 July 1999, subject to a fine for non-compliance.
- 7 The above-mentioned 1997 regulations entered into force on 1 January 1998, which means that the legal basis for the labelling order was an earlier regulation of 1993. However, there is no material difference between the 1993 and 1997 regulations in so far as the disputed points are concerned. The parties are, therefore, in agreement that a judicial review of the order can take place with respect to the 1997 regulations
- 8 The following question was referred to the EFTA Court:

Does the Joint Statement adopted at the meeting of the EEA Joint Committee of 22 June 1995 concerning Annex II Chapter XV, Annex II with subsequent amendments, to the EEA Agreement give Norway the power to introduce a labelling requirement for polyacrylamide that contains a concentration of the residual substance acrylamide which is lower than 0,1%, cf. Council Directive 67/548/EEC of 27 June 1967 with subsequent amendments and Council Directive 88/379/EEC of 7 June 1988, with subsequent amendments?

Legal background

- 9 The question submitted by the national court concerns the interpretation of various provisions of relevant EEA legislation.
- 10 The EEA Agreement Annex II, Chapter XV, Point 1 states *inter alia*:
- “The Contracting Parties agree on the objective that the provisions of the Community acts on dangerous substances and preparations should apply by 1 January 1995. (...) If an EFTA State concludes that it will need any derogation from the Community acts relating to classification and labelling, the latter shall not apply to it unless the EEA Joint Committee agrees on another solution.”
- 11 Article 2(1)(a) to (c) of the Substances Directive reads as follows:
- “(a) “substances” means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

(b) “preparations” means mixtures or solutions composed of two or more substances.

(c) “polymer” means a substance (...).”

12 Article 4 of the Substances Directive reads as follows:

“Classification

1. Substances shall be classified on the basis of their intrinsic properties according to the categories laid down in Article 2(2). In the classification of substances, impurities shall be taken into account as far as the concentration(s) of the latter exceed the concentration limits specified in paragraph 4 of this Article and in Article 3 of Directive 88/379/EEC.

2. The general principles of the classification and labelling of substances and preparations shall be applied according to the criteria in Annex VI, save where contrary requirements for dangerous preparations are specified in separate Directives.

3. Annex I contains the list of substances classified in accordance with the principles outlined in paragraphs 1 and 2, together with their harmonized classification and labelling. The decision to place a substance in Annex I together with the harmonized classification and labelling shall be taken in accordance with the procedure laid down in Article 29.

4. The dangerous substances listed in Annex I shall, where appropriate, be characterized by concentration limits or any other parameter enabling an assessment to be made of the health or environmental hazard of preparations containing the said dangerous substances or substances containing other dangerous substances as impurities.”

13 Article 30 of the Substances Directive reads as follows:

“Free movement clause

Member States may not prohibit, restrict or impede the placing on the market of substances which comply with the requirements of this Directive, on grounds relating to notification, classification, packaging or labelling within the meaning of this Directive.”

14 Section 1.7.2.1 of Annex VI to the Substances Directive regarding “[c]lassification of substances containing impurities, additives or individual constituents,” states, in consonance with the above, that:

“Where impurities, additives or individual constituents of substances have been identified, they shall be taken into account if their concentration is greater than or equal to the limits specified:

- 0,1% for substances classified as ... carcinogenic (category 1 or 2)...

unless lower values have been specified in Annex I to Directive 67/548/EEC. [Annex I contains the List of Dangerous Substances]”

- 15 Section 4.2.1 of Annex VI to the Substances Directive regarding criteria for classification reads as follows:

“4.2.1. Carcinogenic substances. For the purpose of classification and labelling, and having regard to the current state of knowledge, such substances are divided into three categories:

Category 1. Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

Category 2. Substances which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:

- appropriate long-term animal studies,
- other relevant information.

Category 3. Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in Category 2.”

- 16 Article 3(5)(j) of the Preparations Directive states that preparations are to be regarded as carcinogenic:

“(…) if they contain a substance producing such effects (…) in a concentration equal to or exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 of Annex I (Table VI) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.”

- 17 Point 6 of Annex I (Table VI) to the Preparations Directive sets out a concentration limit of minimum 0.1% for carcinogenic substances in Category 1 or 2 which are not listed in Annex I to the Substances Directive with a specific concentration limit.

- 18 The relevant text of the Joint Statement of 1995 reads as follows:

“(…) On the basis of the review which has taken place, Norway has concluded that it accepts the existing Community *acquis*, with effect from 1 July 1995, but with derogations in specific areas. These derogations are listed in Appendix II.

The Contracting Parties take note of these conclusions and agree on the objective that the abovementioned Community acts [Directives 67/548/EEC and 88/379/EEC] should apply fully by 1 January 1999. A new review of the situation will take place during 1998. If an EFTA State concludes that it will still need any derogation from the specific area as set out in its Appendix, the provisions shall not apply to it unless the EEA Joint Committee agrees on another solution. (...)”

The relevant parts of Annex (Appendix) II read as follows:

“The following provisions shall not apply to Norway:

1. As regards Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances:

(a) Article 30, in conjunction with Articles 4 and 5, with respect to:

- (i) the requirements for the classification, labelling and/or specific concentration limits for the substances or groups of substances listed in Annex I to the Directive and shown in the following list. Norway may require the use of different classification, labelling and/or specific concentration limits for these substances. (...)
- (ii) the criteria for classification and labelling of carcinogenic substances as given in Section 4.2.1 of Annex VI to the Directive. Norway may apply different criteria for classification, and different requirements for the application of certain R-phrases.

(b) Article 30 in conjunction with Articles 4 and 6, with respect to the requirements for the classification, labelling and/or specific concentration limits for the substances or groups of substances not listed in Annex I to the Directive and shown in the following list. Norway may require the use of classification, labelling and/or specific concentration limits for these substances;

(...)

2. As regards Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations:

(...)

- (c) Article 13, in conjunction with Articles 3 and 7, with respect to preparations containing substances as defined in points 1(a) to (d).”

19 The relevant text of the Joint Statement of 1999 reads as follows:

“(…) On the basis of the review, which has taken place, Norway has concluded that it accepts the existing Community *acquis*, with effect from 1 January 1999, but with derogations in specific areas. These derogations are listed in the Annex.

The Contracting Parties take note of these conclusions and agree on the objective that the abovementioned Community acts should apply fully by 1 January 2001. A new review of the situation will take place during 2000. If an EFTA State concludes that it will still need any derogation from the specific areas as set out in its Appendix, the provisions shall not apply to it unless the EEA Joint Committee agrees on another solution. (...)”

The relevant parts of the Annex to the Joint Statement of 1999 read as follows:

“The following provisions shall not apply to Norway:

1. As regards Council Directive 67/548/EEC of 27 June on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances:

(a) Article 30, in conjunction with Articles 4 and 5, with respect to:

- (i) the requirements for the classification, labelling and/or specific concentration limits for the substances or groups of substances listed in Annex I to the Directive and shown in the following list. Norway may require the use of different classification, labelling and/or specific concentration limits for these substances; (...)
- (ii) the criteria for classification and labelling of carcinogenic substances as given in Section 4.2.1 of Annex VI to the Directive. Norway may apply different criteria for classification, and provisions regarding impurities, additives or individual constituents in Section 1.7.2.1 of Annex VI to the Directive with regard to substances classified as carcinogens, and different requirements for the application of certain R-phrases.

(b) Article 30 in conjunction with Articles 4 and 6, with respect to the requirements for the classification, labelling and/or specific concentration limits for the substances or groups of substances not listed in Annex I to the Directive and shown in the following list. Norway may require the use of classification, labelling and/or specific concentration limits for these substances; (...)

(...)

2. As regards Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations:

(...)

(c) Article 13, in conjunction with Articles 3 and 7, with respect to preparations containing substances as defined in points 1(a) to (d).”

- 20 Reference is made to the Report for the Hearing for a more complete account of the legal framework, the facts, the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

Findings of the Court

- 21 The national court seeks in essence to know whether the Joint Statement of 1995, with subsequent amendments, gives Norway the power to introduce a requirement that the substance polyacrylamide must be labelled as carcinogenic when it contains the residual acrylamide in a concentration of less than 0.1%.
- 22 The above question mentions “subsequent amendments” to the Joint Statement of 1995. The *Court* takes this to mean a reference to the Joint Statement of 1999. Both statements must, therefore, be taken into consideration when the question is answered.

The 1995 Joint Statement

- 23 In the view of the *Plaintiffs*, the *EFTA Surveillance Authority* and the *Commission of the European Communities*, the Joint Statement of 1995 does not give Norway the power to introduce the contested labelling requirement for polyacrylamide when it contains a concentration of less than 0.1% of the residual substance acrylamide. They base their conclusion mainly on a strict interpretation of point 1(a)(ii) of Annex II to the Joint Statement of 1995. In the view of the *EFTA Surveillance Authority*, however, Norway has this power under the Joint Statement of 1999. The *Commission of the European Communities* supported this view at the oral hearing. According to the *Defendant* and the *Government of Iceland*, both Joint Statements allow Norway to introduce this requirement.

- 24 The EEA rules regarding the classification, packaging and labelling of dangerous substances and preparations are to be found in the Substances Directive and in the Preparations Directive.
- 25 According to Point 1 of Annex II, Chapter XV to the EEA Agreement, the applicability of the Community acts on dangerous substances and preparations, i.e. the Substances Directive and the Preparations Directive, to the EFTA States is contingent on a further decision of the Joint Committee. It is on the basis of this provision that the two Joint Statements of 1995 and 1999 have been adopted. In the Joint Statement of 1995, it is stated that Norway accepts the existing Community *acquis* with effect as of 1 July 1995, with derogations in specific areas as listed in Annex II to that Joint Statement. This provision is repeated in the Joint Statement of 1999, except for the date of entry into force, which is 1 January 1999.
- 26 Article 2(1) of the Substances Directive defines “substances” and “preparations”. According to these definitions, both polyacrylamide and acrylamide are substances, not preparations. It is also clear that acrylamide, as a residual substance in polyacrylamide, is an impurity. Article 2(2) of the Directive defines categories of dangerous substances and preparations. According to Article 2(2), point 1, one of the categories is carcinogenic substances and preparations. Carcinogenic substances and preparations are defined as substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence.
- 27 Article 4(1) of the Substances Directive requires substances to be classified on the basis of their intrinsic properties, according to the categories laid down in Article 2(2). Furthermore, it is stated that, in the classification of substances, impurities are to be taken into account in so far as concentration(s) of the latter exceed the concentration limits specified in Article 4(4) and Article 3 of the Preparations Directive. Article 4(4) of the Substances Directive states that, where appropriate, the dangerous substances listed in Annex I thereof are to be characterized by concentration limits or any other parameter enabling an assessment to be made of the health and environmental hazard of preparations containing the said dangerous substances or substances containing other substances as impurities. Acrylamide is listed as a dangerous substance in Annex I to the Substances Directive, but with no specific concentration limit. Polyacrylamide is not listed at all as a dangerous substance.

- 28 Section 4.2.1 of Annex VI to the Substances Directive defines different categories of carcinogenic substances. According to the classification on the basis of Section 4.2.1, acrylamide is a carcinogenic substance falling in Category 2. Section 1.7.2.1 of Annex VI concerns the classification of substances containing carcinogenic substances as impurities. The section states that a Category 1 or Category 2 carcinogenic substance as an impurity is not to be taken into account unless the concentration thereof is equal to or greater than 0.1% by volume. From this it is clear that, according to the rules set out in the Substances Directive, acrylamide as an impurity is not to affect the classification of polyacrylamide when acrylamide constitutes less than 0.1% of the total volume. Thus, it is clear that, under the rules laid down in the Substances Directive, polyacrylamide is not classified as a carcinogenic substance when the concentration of acrylamide is less than 0.1% by volume.
- 29 The Court notes that, according to Article 3(5)(j) of the Preparations Directive, preparations are to be considered as carcinogenic if they contain a substance producing such effect in concentrations equal to or exceeding either the concentration limits in Annex I to the Substances Directive or the concentration limit specified in point 6 of Annex I (Table VI) to the Preparations Directive, where the substances do not appear in Annex I to the Substances Directive or appear there without concentration limits. According to point 6 of Annex I (Table VI), the concentration limit for a carcinogenic substance in Category 1 is 0.1%.
- 30 Articles 23 to 25 of the Substances Directive provide for rules regarding the labelling of dangerous substances. Article 23(1) provides that necessary measures must be taken to ensure that dangerous substances cannot be placed on the market unless the labelling on their packaging fulfils the requirements set out therein. It is clear from the rules regarding labelling that they must be interpreted in the context of the rules regarding the classification of dangerous substances. Thus, the purpose of labelling must be to reflect accurately the danger of the relevant substance and its classification, in line with the categories laid down in the Directive. Furthermore, the Substances Directive provides for total harmonization in the field of labelling of dangerous substances.
- 31 Consequently, on the basis of the rules set out in the Substances Directive, the presence of acrylamide as an impurity does not give rise to polyacrylamide having to be labelled as carcinogenic, since it constitutes less than 0.1% of the total volume. It must also be emphasized that both Directives aim at laying down an exhaustive set of rules governing the classification, packaging and labelling of substances and that they have not left the Contracting Parties any scope to

introduce other measures in their national legislation, see Case 278/85 *Commission v Denmark* [1987] ECR 4069, at paragraph 12.

- 32 According to the observations submitted by the Plaintiffs, the Defendant, the Government of Iceland, the EFTA Surveillance Authority and the Commission of the European Communities, there does not seem to be any disagreement as to the interpretation of the rules set out in the Directives on this point. Thus, the dispute in the case is limited to the scope of the derogations granted to Norway as provided for in the two Joint Statements.
- 33 As stated above, Norway has, by the Joint Statement of 1995, accepted the existing Community *acquis* with effect as of 1 July 1995, but with derogations in specific areas. These derogations are listed in Annex II to the Joint Statement of 1995. In the Joint Statement of 1995, it is further stated that a new review of the situation was to take place during 1998. This review led to the adoption of the Joint Statement of 1999.
- 34 Annex II to the Joint Statement of 1995 refers to the provisions of the two Directives that are not to apply to Norway. The Court agrees with the observations made by the EFTA Surveillance Authority and the Commission of the European Communities that only point 1(a)(ii) is relevant in the present case.
- 35 As regards the Substances Directive, point 1(a)(ii) of Annex II to the Joint Statement of 1995 states that the criteria for the classification and labelling of carcinogenic substances as given in section 4.2.1 of Annex VI to the Directive are not to apply to Norway. It is furthermore stated that Norway may apply different criteria for classification and different requirements for the application of certain R-phrases.
- 36 The Court is of the view that the wording “(...) different criteria for classification and labelling of carcinogenic substances as given in section 4.2.1. of Annex VI to the Directive” leaves no doubt that Norway may adopt its own system for the classification and labelling of carcinogenic substances. Norway has availed itself of this derogation by adopting its own system for the classification of carcinogenic substances, see most recently Section 24 of Norwegian Regulation No. 1497 of 23 December 1997. However, the wording of point 1(a)(ii), while not a model of clarity, does not give Norway the right to classify substances as carcinogens that may not be classified as such at all under the system laid down in the two Directives. Such a broad interpretation of the wording of point 1(a)(ii) would amount to an exception allowing Norway to classify (within the limits of proportionality) any substance whatsoever as carcinogenic. An interpretation that

would give Norway the power to classify as carcinogenic any substance containing a carcinogenic impurity in whatever low concentration would also go beyond the wording of point 1(a)(ii). In this context, it is noted that point 1(a)(i) and point 1(b) of Annex II to the Joint Statement of 1995 refer to concentration limits, while such limits are not mentioned in point 1(a)(ii). The specific reference to section 4.2.1. supports this interpretation of point 1(a)(ii).

- 37 The Court notes furthermore that the derogation allowing Norway not to apply certain provisions of the Substances Directive constitutes an exception to the fundamental principle of free movement of goods as laid down in Part II of the EEA Agreement (see also recitals 1 and 3 of the Preamble to and Article 30 of the Directive). As held by the Court on previous occasions and as pointed out by the Plaintiffs, the EFTA Surveillance Authority and the Commission of the European Communities, exceptions are, as a rule, to be interpreted narrowly (see Case E-5/96 *Ullensaker kommune and others v Nille AS* [1997] EFTA Court Report 30, at paragraph 33; Case E-9/97 *Erla María Sveinbjörnsdóttir v The Government of Iceland* [1998] EFTA Court Report 95, at paragraph 38; and Case E-1/99 *Storebrand Skadeforsikring AS v Veronika Finanger* [1999] EFTA Court Report 119, at paragraph 33).
- 38 This interpretation is also supported by the fact that point 1(a)(ii) of the Annex to the Joint Statement of 1999 is specific in this regard in stating that Norway has the right not only to apply different criteria for classification, but also different “provisions regarding impurities, additives or individual constituents in Section 1.7.2.1 of Annex VI” to the Substances Directive.
- 39 The Court concludes that point 1(a)(ii) of the Joint Statement of 1995 does not create a sufficient legal basis for Norway to classify polyacrylamide as carcinogenic, even though it contains the carcinogenic substance acrylamide as an impurity, if the concentration of acrylamide is less than 0.1% by total volume.
- 40 On the basis of the foregoing, the Court finds that Annex II to the Joint Statement adopted at the meeting of the EEA Joint Committee on 22 June 1995 concerning the EEA Agreement – Annex II, Chapter XV – regarding the review clauses in the field of dangerous substances, must be interpreted as not giving Norway the power to require polyacrylamide to be labelled as carcinogenic if it contains acrylamide as a residual substance in a concentration of less than 0.1% by total volume.

The 1999 Joint Statement

- 41 As stated above, in the Court's view, the question submitted by the national court also refers to the Joint Statement of 1999.
- 42 Point 1(a)(ii) of the Annex to the Joint Statement of 1999 states that the criteria for the classification and labelling of carcinogenic substances as set out in Section 4.2.1 of Annex VI to the Substances Directive are not to apply to Norway. This sentence reads exactly the same as the one in the corresponding point of Annex II to the Joint Statement of 1995. However, the next sentence states that Norway may apply different criteria for classification, and provisions regarding impurities, additives or individual constituents in Section 1.7.2.1 of Annex VI to the Substances Directive with regard to substances classified as carcinogens, and different requirements for the application of certain R-phrases. A comparison of these two corresponding points shows that the Annex to the Joint Statement of 1999 is, by its wording, wider in scope, since a special reference to Section 1.7.2.1 of Annex VI to the Substances Directives has been added. As mentioned above, that Section contains rules on when impurities are to be taken into account for the purposes of classifying a substance. Special reference is made to the concentration limits for carcinogenic substances.
- 43 The Court is of the view that, from this, it is clear that Norway may set its own rules regarding concentration limits for carcinogenic substances as impurities in other substances. It follows that Norway may set a lower concentration limit for the carcinogenic substance acrylamide as an impurity and thus classify polyacrylamide as carcinogenic if the concentration of acrylamide is equal to or greater than that provided for by its rules. Thus, the conclusion is that Norway may, with reference to point 1(a)(ii) of the Annex to the Joint Statement of 1999, classify polyacrylamide as carcinogenic if it contains acrylamide as an impurity in a concentration equal to or greater than 0.01%.
- 44 From the foregoing, it must be concluded that the Annex to the Joint Statement adopted at the meeting of the EEA Joint Committee on 26 March 1999 concerning the EEA Agreement – Annex II, Chapter XV – regarding the review clauses in the field of dangerous substances, must be interpreted as giving Norway the power to require polyacrylamide to be labelled as carcinogenic if it contains acrylamide as a residual substance in a concentration of equal to or greater than 0.01% by total volume.

Costs

- 45 The costs incurred by the Government of Iceland, the EFTA Surveillance Authority and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, in so far as the parties to the main proceedings are concerned, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the question referred to it by Oslo byrett by the order of 22 February 2000, hereby gives the following Advisory Opinion:

Annex II to the Joint Statement adopted at the meeting of the EEA Joint Committee on 22 June 1995 concerning the EEA Agreement – Annex II, Chapter XV – regarding the review clauses in the field of dangerous substances, must be interpreted as not giving Norway the power to require polyacrylamide to be labelled as carcinogenic if it contains acrylamide as a residual substance in a concentration of less than 0.1% by total volume.

The Annex to the Joint Statement adopted at the meeting of the EEA Joint Committee on 26 March 1999 concerning the EEA Agreement – Annex II, Chapter XV – regarding the review clauses in the field of dangerous substances, must be interpreted as giving Norway the power to require polyacrylamide to be labelled as carcinogenic if it contains acrylamide as a residual substance in a concentration of equal to or greater than 0.01% by total volume.

Thór Vilhjálmsson

Carl Baudenbacher

Per Tresselt

Delivered in open court in Luxembourg on 14 July 2000.

Gunnar Selvik
Registrar

Thór Vilhjálmsson
President