REPORT FOR THE HEARING

in Case E-2/00
Revised*

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");

– 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");

– 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,[1] in particular Annex II to that Joint Statement, setting up certain derogations concerning Norway, hereinafter the "Joint Statement of 1995";

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* The fourth indent of legislation at the top of page 2 and points 10, 39 and 85

1 OJ 1996 C 6, p. 7, 11.1.96.

– 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,[2] in particular the Annex to that Joint Statement, setting up certain derogations concerning Norway, hereinafter the "Joint Statement of 1999".

I. Introduction

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 Development (hereinafter the "Defendant").

2. The dispute before the national court involves 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 exceeds 0.01% by weight. The limit in the rest of the European Economic Area is 0.1% by weight.

II. Legal background

3. The question submitted by the national court concerns the interpretation of various provisions of relevant EEA legislation.

4. 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."*

5. 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.*

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[2] OJ 1999 C 185, p. 6, 1.7.1999.

(c)"polymer" means a substance (...)".

6. 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."

7. 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."

8. 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[3] *to Directive 67/548/EEC."*

9. 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."

10. 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[3] *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. (…)"* [footnote added]

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

"The following provisions shall not apply to Norway:

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[3] Annex I contains the List of Dangerous Substances.

[3] Directives 67/548/EEC and 88/379/EEC.

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).”

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; (...)*
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> *(...)*
>
> *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)."*

11. Article 3(5)(j) of the Preparations Directive states that preparations shall 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."*

12. 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.

13. The contested Norwegian legislation in the case before the national court is Regulation No. 996 of 21 August 1997 relating to the classification, labelling, etc. of dangerous chemicals, and Regulation No. 1497 of 23 December 1997 relating to criteria for the classification of dangerous chemicals.

14. Section 3 of Regulation No. 996 of 21 August 1997 relating to the classification, labelling etc. of dangerous chemicals contains the following definitions:

> *"Substances: chemical elements and their compounds in the natural state or obtained by any production process. This also includes 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.*
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> *Preparations: solutions or solid, liquid or gaseous mixtures composed of two or more substances."*

15. Section 4 of the same regulation states:

> *"Substances shall be classified on the basis of their intrinsic properties, and shall be placed in one or more of the danger categories laid down in section 6."*

16. Section 18 of Regulation No. 1497 of 23 December 1997 relating to criteria for the classification of dangerous chemicals provides with respect to the "Classification of substances containing impurities and/or additives":

> *"With the exception of the substances appearing in the List of Dangerous Substances, classification with respect to health hazards of substances containing impurities, additives or individual constituents shall be carried out in the same way as for preparations (…)".*

17. Section 24 of the same regulation provides with respect to "Classification of substances and preparations with respect to carcinogenic properties" in Point 1, second and third paragraphs:

"The classification of carcinogenic substances is divided into two steps: firstly, a substance is evaluated to determine whether or not it is carcinogenic on the basis of any results available from studies, and secondly the dose-response relationship is assessed to decide the potency of the substance as a carcinogen. On the basis of these results, carcinogenic substances are classified in three groups (K1, K2 and K3).

Preparations are classified solely on the basis of the concentrations of their constituents and the classification of these. Tests of preparations on animals may not be used as a basis for classification."

18. With respect to the classification of preparations, Section 24, Point 3 states:

"Classification of preparations with respect to carcinogenic effects shall always be based on the classification of their constituent substances in accordance with subsection 2 above and their concentrations in the preparation.

Carcinogenic substances shall be taken into account in the classification of a preparation if their concentrations in the preparation are equal to or greater than:

- *0.01 % for substances classified in group K1*
- *0.1 % for substances classified in group K2*
- *1.0% for substances classified in group K3*

unless specific concentration limits are given in the List of Dangerous Substances."

III. Facts and procedure

19. Polyacrylamide is a chemical substance produced through a polymerization of the substance acrylamide. The presence of acrylamide in polyacrylamide is residual from the chemical production of polyacrylamide. Both the European Union (EU) and Norway consider acrylamide to be a carcinogenic substance.

20. Polyacrylamide is produced and distributed all over the world and has numerous areas of application. It is used in particular in the process industries, mainly in the cleansing of industrial and municipal wastewater and in the wood-processing industry. In Europe, the product is also used for the purification of drinking water.

21. 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 the product.

22. 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[4] (hereinafter "the Working Environment Act"). The Labour Inspection adopts *inter alia* administrative regulations and decisions concerning 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.

23. On 9 April 1997, the Labour Inspection ordered the importers of polyacrylamide to classify and label polyacrylamide products containing more than 0.01% by weight 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.

24. The 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.

25. 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 is contrary to EEA law.

26. 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.

27. 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.

28. 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 coercive fine.

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[4] Act No. 4 of 4 February 1977 relating to Worker Protection and Working Environment.

29. 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.

30. Against this background, Oslo byrett decided to submit a request for an Advisory Opinion to the EFTA Court.

IV. Question

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?**

V. Written Observations

31. Pursuant to Article 20 of the Statute of the EFTA Court and Article 97 of the Rules of Procedure, written observations have been received from:

– 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, acting as Agents.

Allied Colloids and Others

32. The Plaintiffs note that Point 1(a)(ii) of the Joint Statement of 1999 exempts Norway from having to comply with the requirement for the classification and labelling of carcinogenic substances as set out in Section 4.2.1 of Annex VI to the Substances Directive. The provision is not only a statement of the inapplicability of certain provisions of the Directive, but also an indication of the lawful scope of differences in national regulation in the area.

33. The Plaintiffs point out several grounds on which Norway is precluded from imposing a labelling requirement for polyacrylamide that contains a concentration of under 0.1% of the residual substance acrylamide.

34. Firstly, it is important to take into consideration that, unlike Point 1(a)(i), which allows the use of "specific concentration limits", Point 1(a)(ii) only subjects "classification and labelling" to requirements which are different from those of the Directive. A comparison of the wording of Points (i) and (ii) shows that the possibility of applying different requirements for classification and labelling does not allow room for applying different *concentration limits* which have an impact on the classification.[6] If this had been the intention of the drafters, it would not have been necessary to refer specifically to the alteration of concentration limits in Point 1(a)(i).

35. Secondly, this interpretation is supported by the amplification to the same effect in Point 1(b) which, unlike Point 1(a)(ii), also distinguishes between different classification, labelling and specific concentration limits.

36. Thirdly, prior to the Joint Statement of 1999, the exemption was limited to the application of criteria for classification of carcinogens which differ from those set out in Section 4.2.1 of the Directive, and from requirements for the application of certain R-phrases. In the view of the Plaintiffs, it is obvious that Point 1(a)(ii) of the Joint Statement of 1995 did not give Norway the latitude to maintain concentration limits other than those following from the Preparations Directive. It is not disputed that the wording of the Joint Statement of 1995 has been amended. It has, however, never been demonstrated that the purpose was to alter the meaning of the provision. If the intention was to make way for other concentration limits for carcinogenic impurities etc., reference should have been made to the basic provision in Article 3(5)(j) of the Preparations Directive. This is the only provision relevant to the classification of carcinogens pursuant to

6 Reference is made to Article 4(1) and (4) of the Substances Directive.

Article 4(1) and (4) of the Substances Directive, and is only reflected in the subordinated provision in Section 1.7.2.1 of Annex VI to the Substances Directive.

37. As to the applicability of Point 2(c), which makes a derogation from *inter alia* Article 3 of the Preparations Directive, to polyacrylamide, the Plaintiffs argue that this substance is not "defined in Points 1(a) to (d)" within the meaning of that provision. The substance is not listed in any of the derogations in Points 1(a)(i) or (b) to (d). Point 1(a)(ii), however, encompasses "carcinogenic substances as given in Section 4.2.1 of Annex VI to the [Substances] Directive". It is the opinion of the Plaintiffs that, in light of the vagueness of this passage compared to the preciseness of Points 1(a)(i), 1(b) and 1(d), a narrow interpretation is necessary and that, consequently, Point 1(a)(ii) does not suffice as a definition of "substances".

38. In support of this interpretation, the Plaintiffs argue that the reference to the substances listed in Points 1(a) and 1(b) is necessary due to the interrelation between the Substances Directive and the Preparations Directive. The references to Points 1(c) and 1(d) have to be considered as a basis for applying the differing labelling provisions on preparations as well.

39. In support of such a narrow interpretation, the Plaintiffs point out that if Norway could decide on a different concentration limit for any carcinogenic substance appearing in the List of Substances, in addition to the other specially listed substances (which may also be classified as carcinogens, see e.g. the Norwegian classification of Ethyl acrylate and Trichlorometan in Norway's list of Substances), then the power to derogate would be extremely broad indeed. This would obviously be incompatible with the Joint Statement of 1999, which permits derogations only under defined circumstances. Additionally, if the derogation were to be so broad, it would be difficult to understand why the Preparations Directive was to apply to Norway.

40. The Plaintiffs argue that any different national legislation on the subject-matter would restrict the free movement of chemicals which fulfils the harmonized requirements as set out in the different directives. The free movement of goods is one of the four freedoms contained in the EEA Agreement and is explicitly provided for in Article 11 EEA. It is a general interpretation principle of EEA law that preference should be given to the interpretation that renders the provision consistent with the Agreement, rather than the interpretation that leads to its being incompatible with the Agreement.[5] Any ambiguity in the Joint Statement of 1999 is subject to this interpretation

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[5] References are made to Case E-1/94 *Ravintoloitsijain Kunstannus Oy Restamark* [1994-1995] EFTA Court Report 15, paragraph 56; Case 46/76 *Bauhuis* v *Netherlands* [1977] ECR-5, paragraph 15; Case 252/83 *Commission* v *Belgium* [1986] ECR-3742, paragraph 12; and *EU Karnov* (sixth edition, 1999), at p. 1855.

principle, which must apply equally to exceptions to harmonized areas and to the provisions of the Agreement.

41. The Plaintiffs add that no papers have been produced demonstrating that the views of the Defendant are the Contracting Parties' joint views. Unilateral declarations of intention are not relevant for interpretative purposes.[6]

42. As to the question of whether the Plaintiffs' submissions will lead to a different regulation of deliberate additions of carcinogenic substances and of carcinogenic substances that turn out to be unavoidable impurities, the Plaintiffs argue that this will not be the case. The Plaintiffs refer to their previous argument and submit that no different concentration limits may be adopted with respect to substances which are not defined in Point 2(c). Thus, the concentration limit will remain the same regardless of whether the acrylamide is a deliberate addition or an unavoidable impurity.

43. The Plaintiffs propose that the question be answered as follows:

> *"The Joint Statement adopted at the meeting of the EEA Joint Committee of 22 June 1995 concerning Annex II Chapter VI, Annex II with subsequent amendments, to the EEA Agreement, does not 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%, see 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."*

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

44. It is the view of the Defendant that both the negotiation process and the information exchanged between Norway and the Commission, as well as the text of the Joint Statements, show that Norway is entitled to set a concentration limit for the presence of acrylamide in polyacrylamide which is different from the one applicable in the EU. The Defendant holds that it is Point 1(a)(ii), as it stands in the Joint Statement of 1999, which forms the legal basis for the Norwegian rules and the contested order.

45. The Defendant is of the view that the derogation in Point 1(a)(ii) is to be regarded as an umbrella provision that grants Norway a derogation in relation to all substances characterized as carcinogenic, cf. Section 4.2.1 of Annex VI to the Substances Directive. This derogation gives Norway the power to have a system of classification different from the one used in the EU, with the consequence that

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6 Reference is made to Gulmann/Hagel-Særensen, *EU-ret* (third edition), at p. 159.

Norway may classify substances as carcinogenic even if they are not classified as such in the EU.

46. The Defendant notes that the wording of the provision gives Norway a derogation for "the criteria for classification and labelling of carcinogenic substances", without explicitly mentioning "concentration limits". This does not, however, prevent Norway from having its stringent concentration limit for substances containing high-potency carcinogenic impurities. Such an interpretation would be overly narrow, as account must also be taken of both the connection between the derogations in the Joint Statement of 1999 and the way it is structured. Furthermore, importance must be attached to the connection between the EU Substances Directive and Preparations Directive and the respective classification systems in the EU and Norway.

47. Point 1(a)(ii) is a derogation that refers exclusively to the Substances Directive. This Directive contains the specific concentration limits, whereas the Preparations Directive contains the general concentration limits. Norway has been granted a derogation for four specific substances, which appear in the Substances Directive with specific concentration limits, cf. Point 1(a)(i) of the Annex.

48. Otherwise, there are no provisions in the Substances Directive regarding concentration limits for substances. The reason for this is that substances, cf. Article 2(1)(a) of the Substances Directive, are by definition pure substances, and it is thus not relevant to apply concentration limits in respect of them.

49. The need for concentration limits arises only when the carcinogenic substances occur together with other substances in some form of mixture, and then in order to establish a "cut-off point" at which the preparation is to be classified, on the basis of the classification of the carcinogenic substance.[7]

50. Accordingly, acrylamide, which is not shown with a specific concentration limit on the List of Dangerous Substances, is to be classified on the basis of the general concentration limit in the Preparations Directive.[8]

51. Norway has a derogation from this limit for preparations containing carcinogenic substances which are specified under Point 1(a) to (d) of the Joint Statement of 1999. The Defendant points out that polyacrylamide contains the impurity acrylamide, which is a substance referred to under Point 1(a)(ii) of the derogation.

52. Since under Point 2(c) Norway may prescribe a more stringent concentration limit than the EU limit of 0.1% set out in the Preparations Directive, Norway must be allowed to apply different rules for the classification

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7 Reference is made to Article 3 of the Preparations Directive.

8 Reference is made to Point 2(c) of the Annex to the Joint Statement of 1999.

and labelling of both carcinogenic preparations and substances, including acrylamide.

53. The Defendant is of the view that Point 1(a)(ii) must be interpreted in conjunction with Point 2(c), so as to give equal treatment to preparations with acrylamide deliberately added and substances where acrylamide occurs as an unintended result of the production process.

54. The Defendant argues that an attempt is made in the directives to achieve this uniform treatment and that there would be little consistency between the rules if substances containing impurities were to be treated differently from preparations containing deliberately-added substances. Moreover, there are no health-related reasons to differentiate between concentration limits in this context.

55. In addition to being illogical, applying different concentration limits for substances or substances with impurities and preparations would also be at variance with both the EU and the Norwegian systems for classifying carcinogenic chemicals. Consequently, the derogation in Point 1(a)(ii) of the Annex to the Joint Statement of 1999 must mean that Norway may derogate from the rules governing the classification of substances that contain impurities.[9]

56. The Defendant goes on to point out that the Joint Statement of 1999 refers to Section 1.7.2.1 of Annex VI to the Substances Directive and not to Article 3(5)(j) of the Preparations Directive. This reference was added to the Joint Statement of 1999 as a more precise specification of the scope of the derogation.

57. The 1999 derogation is worded in general terms: Norway has a derogation with respect to "provisions regarding impurities". This supports the proposition that the derogation in respect of impurities is a general one, i.e. it is not limited to classification, meaning that it also covers provisions regarding concentration limits. Referring to the above arguments concerning equal treatment of deliberately-added acrylamide and acrylamide as an impurity, the Defendant maintains that there is nothing justifying a more narrow interpretation.

58. The specification, which does not imply any extension of the derogation on this point, contains special rules for the classification of substances that contain carcinogenic impurities. Under Section 1.7.2.1, impurities are to have the same concentration limit as preparations, which is 0.1% for carcinogenic substances in EU categories 1 and 2.[10] The Defendant cannot see any grounds for maintaining that Norway is bound by this limit for impurities.

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9 Section 1.7.2.1 of Annex VI to the Substances Directive.

10 Reference is made to the classification system, i.e. to Section 4.2.1 of Annex VI, which sets out the EU classification system.

59. The rules in Section 1.7.2.1 of Annex VI to the Substances Directive relating to "Classification of substances which contain impurities, additives or individual constituents" are in conformity with the rules laid down in the directives.[11] There is no conflict between the respective rules set out in the Substances Directive and the Preparations Directive. The Defendant argues in effect that the derogation would not have been interpreted any differently had there been a reference to Article 3(5)(j) of the Preparations Directive instead of to Section 1.7.2.1 of Annex VI of the Substances Directive. The Defendant argues, with reference to Section 1.7.2.1, that there are no grounds to interpret the derogation more narrowly as there is nothing in Article 3 of the Preparations Directive that is not also in Section 1.7.2.1 of Annex VI to the Substances Directive.

60. The Defendant also refers to the fact that it is in Annex VI to the Substances Directive that the criteria for the classification of carcinogenic chemicals are regulated in detail. It is therefore logical to refer to the relevant Section of the Annex to the directive, i.e. Section 1.7.2.1. According to its wording, Annex VI to the Substances Directive determines "general criteria", i.e. the general principles for the classification of substances and preparations which are dealt with in Article 4 of the Substances Directive and Article 3 of the Preparations Directive, cf. Section 1.2 of Annex VI. Furthermore, it is the annexes to the Substances Directive that contain the substantive content of the directive. The subsequent amendments that have been made to the directive were made to the annexes to the directive and not to the text of the directive itself.

61. Accordingly, the Defendant asserts that Point 1(a)(ii) of the Joint Statement of 1999 amounts to an explicit authorization for Norway to prescribe rules for the classification and labelling of carcinogenic impurities, including concentration limits, which differ from the EU rules.

62. Any other interpretation would render the reference to Section 1.7.2.1 of Annex VI pointless and this, in the view of the Defendant, is unlikely. The Defendant argues that it is logical, on the basis of the EU system, to make the limit for impurities the same as the limit for preparations. It is equally logical for the derogations to allow Norway to maintain that the reference to Section 1.7.2.1 is to be accorded substantive weight. The derogation granted to Norway must also encompass this limit.

63. In the view of the Defendant, it is clear that even before this explicit specification was included in the Joint Statement of 1999, Norway had a general derogation with respect to concentration limits for carcinogenic preparations, substances and substances containing impurities. This is particularly true since the Contracting Parties were aware when the EEA Agreement was entered into that Norway applied a limit of 0.01% to carcinogenic substances.

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[11] Article 4 (1) of the Substances Directive, cf. Article 3 (5)(j) of the Preparations Directive.

64. The Defendant asserts that the Norwegian limit of 0.01% is authorized by the derogation in the Joint Statements of 1995 and 1999. In interpreting these derogations, importance should be attached to the fact that Norway previously had a total derogation. At the time of the negotiations, which resulted in the Joint Statement of 1995, the EU was aware that Norway needed derogations due to its particularly high safety standards and that this was of great political importance to Norway.

65. In support of the above, the Defendant notes that Point 1(b) of the Joint Statement of 1999 gives Norway the power to have different criteria for the classification and labelling of, and different concentration limits for, certain substances which do not appear on the List of Dangerous Substances. This derogation does not apply to substances that have been classified as carcinogenic, since these substances are regulated by the general derogation in Point 1(a)(ii), but to substances that are classified as toxic, sensitizing to skin, very toxic, etc. Consequently, this provision cannot be interpreted as exclusively regulating the power to prescribe different/more stringent concentration limits for acrylamide in polyacrylamide.

66. The Defendant further argues that the fact that Point 2(c) of the Joint Statement of 1999 only covers "preparations" is not decisive in this case, although polyacrylamide is a substance with an impurity. The substance is to be treated in the same way, regardless of whether it is a deliberate addition/preparation or an impurity, since they would have the same classification.

67. In the view of the Defendant, it would be an error to interpret Point 2(c) as being a derogation only for preparations that contain substances on the List of Dangerous Substances, since this would leave different concentration limits to apply to preparations and to substances containing impurities. Such an interpretation would also eliminate any practical application of the derogation with respect to carcinogenic substances, since no carcinogenic substances appear on any list under Point 1. Such an interpretation would be at variance with the intention and premisses for the negotiations on the derogations.[12]

68. The Defendant proposes that the question be answered as follows:

> *"The Joint Statement adopted at the meeting of EEA Joint Committee of 22 June 1995 concerning Annex II Chapter XV, Annex II with subsequent amendments, to the EEA Agreement does 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%."*

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12 Reference is made *inter alia* to quotations of *travaux préparatoires* relating to the EEA Agreement.

The Government of Iceland

69. The Government of Iceland emphasizes that the aim of the derogations clearly was to allow Norway to apply, for a limited period of time, different rules than those contained in the directives.

70. The Government of Iceland submits that the Norwegian application of the rules in question can be based on Point 1(a)(ii) of the Joint Statement of 1999. This provision should be interpreted as an umbrella provision that regulates all substances that are classified as carcinogenic.[13]

71. The word "criteria" in the provision must be interpreted so as to allow Norway to use concentration limits other than those contained in the directives as a basis for imposing a labelling requirement for carcinogenic substances.

72. The Government of Iceland also points out that the Norwegian rules are based on Point 2(c) of the Joint Statement of 1999, since acrylamide is regarded as a carcinogenic substance which is covered by Point 1(a)(ii) referred to in Point 2(c).

73. The Government of Iceland proposes that the question be answered as follows:

> *"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 gives 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."*

The EFTA Surveillance Authority

74. The EFTA Surveillance Authority notes that the Joint Statement of 1995 formed the legal basis for the labelling order issued by the Labour Inspection on 9 April 1997, and points out that this text does not mention concentration limits set for impurities in Section 1.7.2.1 of Annex VI to the Substances Directive.

75. This omission is, in the view of the EFTA Surveillance Authority, all the more noteworthy as the derogation possibilities under Points 1(a)(i) and 1(b) specifically mention the possibility of using different concentration limits for the listed substances. Thus, the wording of this derogation and its context clearly point in favour of considering that Norway may not deviate from the concentration limits set out in the Substances Directive.

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[13] Reference is made to Annex VI, Section 4.2.1 of the Substances Directive.

76. The EFTA Surveillance Authority also points out that it seems probable that Norway intended to be able to deviate from the concentration limits set out in Section 1.7.2.1 of Annex VI to the Substances Directive. It is also possible to argue that classification of substances is closely linked to the question of applicable concentration limits and that, therefore, the derogation in Point 1(a)(ii) should be interpreted broadly so as to include concentration limits.

77. However, the EFTA Court has previously been confronted with the situation where the wording of an exception clause for an EFTA State does not reflect the wide scope of application that the EFTA State possibly intended it to have.[14] In that case, the EFTA Court upheld a literal interpretation.

78. The EFTA Surveillance Authority also points out that a strict interpretation will not make the exception possibly granted through Point 1(a)(ii) objectively void of its purpose, as Norway will still undoubtedly be allowed to classify carcinogenic substances based on different criteria than those found in the directives.

79. As the rules in Annex VI are addressed not only to national authorities, but also concern manufacturers and importers, a strict interpretation would be in line with the principle of legal certainty common to all EEA States. The European Court of Justice has repeatedly held that Community legislation must be certain and its application must be foreseeable for individuals.[15] A strict interpretation would also be in line with the principle *patere legem quam ipse fecisti*.[16] Furthermore, in line with the consistent case law of the EFTA Court and the European Court of Justice, derogations have to be interpreted restrictively.

80. The EFTA Surveillance Authority is of the opinion that the Joint Statement of 1995 does not cover the Norwegian labelling instruction. However, the added reference in the Joint Statement of 1999 to Section 1.7.2.1 of Annex VI to the Substances Directive leads to the conclusion that the Joint Statement of 1999 covers the instruction.

81. The EFTA Surveillance Authority proposes that the question be answered as follows:

> *"Annex II of the Joint Statement adopted at the meeting of the EEA Joint Committee of 22 June 1995 concerning Annex II Chapter XV to the EEA Agreement is to be interpreted so as not to permit the introduction of a labelling requirement for polyacrylamide that contains a concentration of the residual substance acrylamide which is lower than 0,1%, cf. Council Directive*

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14 Reference is made to Case E-9/97 *Erla María Sveinbjörnsdóttir* v *The Government of Iceland* [1998] EFTA Court Report 95.

15 Reference is made to Case T-115/94 *Opel Austria* v *Council* [1997] ECR II-39, paragraph 26; and Case 70/83 *Gerda Kloppenburg* v *Finanzamt Leer* [1984] ECR 1075, paragraph 1.

16 Reference is made to Case T-331/94 *IPK* v *Commission* [1997] ECR II-1665, paragraph 45; and Case C-39/93 P *SFEl* v *Commission* [1994] ECR I-2681, paragraph 18.

67/548/EEC of 27 June 1967 with subsequent amendments and Council Directive 88/379/EEC of 7 June 1988, with subsequent amendments.

The Annex of the Joint Statement adopted at the meeting of the EEA Joint Committee of 26 March 1999 concerning Annex II Chapter XV to the EEA Agreement is to be interpreted so as to permit such a labelling requirement."

The Commission of the European Communities

82. The Commission of the European Communities refers initially to the derogation set out in Annex II Chapter XV to the EEA Agreement, which recognizes that the standards for dangerous substances and preparations were more stringent in some EFTA Contracting Parties, and that EU legislation was intended to evolve towards higher standards as more scientific evidence evolved. The position was therefore left open-ended, leaving to each of the EFTA Contracting Parties the right to decide for itself whether it requires a derogation from the Community legislation on classification and labelling.

83. Since the Joint Statement of 1995 formed the legal basis for the labelling order issued by the Labour Inspection on 9 April 1997, the Commission takes this as the basis for its legal assessment.

84. According to the Commission, this derogation permits Norway to set labelling standards at more stringent levels than are permitted under EC legislation.

85. The Commission is of the opinion that polyacrylamide is a substance according to the definitions in the Substances Directive and the Preparations Directive. With reference to Article 4 and Section 1.7.2.1 of Annex VI to the Substances Directive, the Commission observes that impurities may affect the classification and labelling of a substance if the concentration exceeds a certain limit based on either the specific concentration limits in the List of Dangerous Substances in Annex I to the Substances Directive, or the general limit in Article 3 of the Preparations Directive, or Section 1.7.2.1 of Annex VI to the Substances Directive.

86. Acrylamide is listed in the Dangerous Substances List, but without a specific concentration limit. It is classified as carcinogenic, category 2, in accordance with the criteria laid down in Section 4.2.1 of Annex VI to the Substances Directive. Therefore the classification and labelling will be linked to the 0.1% concentration limit for impurities in substances of such classification, as given in Section 1.7.2.1 of Annex VI. This is the same limit as the general limit in Article 3 of the Preparations Directive.

87. The Norwegian derogation as laid down in the Joint Statement of 1995, in particular Point 1(a)(ii), allows Norway to apply criteria for classification and

labelling of carcinogenic substances which differ from those given in Section 4.2.1 of Annex VI to the Substances Directive.

88. The Norwegian criteria for the classification of carcinogens do deviate from the Community criteria, since Norway classifies acrylamide as a carcinogen in "K1", which is the group with the carcinogens of the highest potency. Norway has also established its own concentration limits with respect to preparations in accordance with the derogation under Point 2(c) of the Joint Statement of 1995.

89. The Commission states that the derogation in the Joint Statement of 1995 can be interpreted in two ways. One interpretation is that, since Norway can derogate from the criteria for classification in Section 4.2.1 to Annex VI to the Substances Directive, it must as a consequence be able to derogate from the concentration limits laid down in Section 1.7.2.1 of Annex VI. The other possibility is to read the derogation narrowly, and conclude that since the provision in Section 1.7.2.1 of Annex VI is not explicitly exempted, it still applies. Similarly, it can be argued that the renegotiated Joint Statement of 1999 specifically adds a reference to Section 1.7.2.1 of Annex VI to the Substance Directive and can therefore be seen as constituting a widening of Norway's derogation.

90. The EEA Agreement has as its objective to establish a homogeneous European Economic Area and to maintain uniform interpretation and application of the EEA Agreement. Article 6 EEA provides that the Agreement shall be interpreted in conformity with the relevant rulings of the European Court of Justice. The European Court of Justice has consistently held that derogations shall be interpreted narrowly.

91. The Commission is therefore of the view that polyacrylamide cannot, according to the wording of the Joint Statement of 1995, be classified and labelled contrary to the concentration limits provided for in Section 1.7.2.1 of Annex VI to the Substances Directive.

92. The Commission of the European Communities proposes that the question be answered as follows:

> *"Annex II of the Joint Statement concerning the EEA Agreement - Annex II, Chapter XV - adopted at the meeting of EEA Joint Committee on 22 June 1995, as regards Council Directive 67/548/EEC as amended and Council Directive 88/379/EEC as amended, does not give Norway the power to introduce a requirement concerning the labelling of polyacrylamide as carcinogenic where it contains a concentration of the residual substance acrylamide which is lower than 0,1% by weight."*

Thór Vilhjálmsson
Judge-Rapporteur