OPINION OF ADVOCATE GENERAL MISCHO

delivered on 21 March 2000 *

I — The question

1. By order of 17 December 1998, the Kammarrätten i Stockholm (Administrative Court of Appeal, Stockholm) referred the following question to the Court for a preliminary ruling under Article 177 of the EC Treaty (now, after amendment, Article 234 EC):

'Having regard to its aim, is a prohibition against the industrial use of trichloroethylene as described in the order for reference consistent with Article 36 of the EC Treaty and its application in Community law, even if it contravenes Article 30 of the Treaty?'

II — The main proceedings

2. Paragraph 12 of Swedish Law 1985:426 on chemical products [1] (hereinafter 'Law 1985:426') provides that the Swedish Government, or the administrative authority appointed by it, may prohibit the treatment, import or export of a chemical product if there are specific health or environmental protection reasons for doing so.

3. In the exercise of that power, the Swedish government enacted Regulation 1991:1289 on certain chlorinated solvents (hereinafter 'the regulation'). [2]

4. Article 2 of that regulation prohibits the sale, transfer or use, for industrial purposes, of chemical products composed wholly or partially of methyl chloride or trichloroethylene.

* Original language: French.

1 — Lagen (1985:426) om kemiska produkter, replaced by the Environmental Code (Miljobalken 1998:808) which entered into force on 1 January 1999.

2 — Forordningen (1991:1298) om vissa klorerade losningsmedel, replaced by Regulation 1998:944 concerning prohibition and other provisions applicable to certain situations where chemical products are treated, imported and exported, which entered into force on 1 January 1999.

5. The prohibition on using trichloroethylene for industrial purposes came into force on 1 January 1996.

6. However, Article 3 of the regulation enables the Kemikalieinspektionen [3] to grant general exemptions where they are justified on specific grounds, and individual exemptions where there are 'special' reasons for doing so.

7. On the basis of that regulation, the Chemicals Inspectorate adopted the KIFS 1995:6 rules on exemptions from the prohibitions contained in the regulation [4] (hereinafter 'KIFS 1995:6'), which also came into force on 1 January 1996.

8. KIFS 1995:6 provides for both a general exemption to the prohibition on the use of trichloroethylene for research and analysis until the end of 1996 and the right to grant exemption in special cases.

9. Under Article 1(2) of KIFS 1995:6 undertakings experiencing temporary difficulties notified in accordance with the provisions of Article 4 were allowed to use trichloroethylene for degreasing and drying until the end of 1996.

10. Under Article 4 of KIFS 1995:6 undertakings experiencing temporary difficulties and which considered that they needed to use trichloroethylene for degreasing and drying during 1996 could do so subject to certain conditions. In particular, they were to notify the Chemicals Inspectorate of their intention, they were not to begin using the substance until they had received acknowledgment of their application to do so and had paid the appropriate duties, and the application had to give an estimate of the amount of the substance used at each place of work, indicate the methods used, explain the temporary difficulties encountered and, above all, explain how and when the applicant proposed to resolve them.

11. Under that Article, the applicant also had to state whether the request also constituted an application for exemption for the period subsequent to the transitional period.

12. Finally, Article 5 of KIFS 1995:6 provided that the Chemicals Inspectorate

3 — Chemicals Inspectorate.

4 — Kemikalieinspektionen föreskrifter om undantag fran förbud i fördordningen (1991:1289) om vissa klorerade lösningsmedel, KIFS 1995:6.

would publish a decision setting out the cases in which the uses of trichloroethylene specified in pursuance of Article 2 might also be authorised after 31 December 1996.

13. KIFS 1995:6 was amended in 1996 and 1997 by KIFS 1996:8 and 1997:3.[5]

14. Following the 1996 amendment, undertakings which had made a declaration that they were experiencing temporary difficulties and had received a written confirmation from the Chemicals Inspectorate were allowed to continue to use trichloroethylene for degreasing and drying until 31 March 1997.

15. KIFS 1997:3, which came into force on 1 April 1997, contains a new Article 1(a) under which a presumption of 'special reasons' arises where the applicant undertaking can show that:

'1. it is continuing to investigate feasible alternatives;

2. no practicable alternative has been found to solve the problem;

3. its use [of trichloroethylene] does not entail unacceptable exposure.'

16. Since that amendment came into force, the Chemicals Inspectorate therefore no longer required, as it had with earlier applications, the applicant to submit a plan showing when and how trichloroethylene would cease to be used.

5 — They have since been replaced by KIFS 1998:8, section 4, chapter 9.

17. Toolex Alpha AB, a company incorporated under Swedish law (hereinafter 'Toolex'), is a manufacturer of machine parts which are used in the production of compact discs. It uses trichloroethylene to remove residues of grease produced during the manufacturing process.

18. It was one of 220 or so undertakings, which applied in 1996 for permission to continue using trichloroethylene after March 1997.

19. By decision of 18 June 1996, the Chemicals Inspectorate rejected Toolex's application, essentially on the ground that, like 90% or so of the other applicant undertakings, it was unable to submit a plan showing how and above all when the use of trichloroethylene would be discontinued.

20. Toolex brought an action against that administrative decision before the Länsrätten i Stockholmslän (County Administrative Court, Stockholm) which, by judgment of 27 November 1996, annulled the Chemical Inspectorate's decision on the ground that the Swedish legislation relating to the matter was inconsistent with Community law in that regard.

21. Following the appeal lodged by the Chemicals Inspectorate, the Kammarrätten referred the question now in issue to the Court of Justice for a preliminary ruling.

22. As I have just explained, the Swedish rules on the use of trichloroethylene were amended on several occasions whilst the main proceedings were pending.

23. After the provisions relating to exemptions were amended on 1 April 1997 pursuant to KIFS 1997:3, several undertakings, including Toolex, whose applications had had to be rejected in 1996, reapplied for, and were subsequently granted, authorisation under the new rules to use trichloroethylene after March 1997.

III — Appraisal

24. I shall concentrate my analysis on the pleas of the Swedish Government and the Commission for two reasons: first, Toolex, the defendant in the main proceedings, has essentially confined itself to emphasising the harmful financial consequences which it claims the prohibition on using trichloroethylene might have for numerous undertakings in the absence of any satisfactory alternative; and second, the Chemicals Inspectorate, the applicant in the main proceedings, essentially endorses the observations submitted by the Swedish Government.

A — *Appraisal in relation to secondary Community law*

25. The Commission submits, first, that the Kingdom of Sweden prohibited the use of trichloroethylene for industrial purposes with a view to introducing a more rigorous reclassification of that substance than that afforded by 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 [6] (hereinafter 'the classification directive'). It takes the view that the Kingdom of Sweden is thereby contravening not only the procedure laid down under Article 31, [7] but also the provision on free movement contained in Article 30 of the classification directive, under which: '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.'

26. The Swedish Government contests that view.

27. I too am unable to share the Commission's view. There is nothing in the documents in the case or in the submissions made at the hearing to show that the Swedish legislature prohibited the use of trichloroethylene on grounds relating to notification, classification, packaging or labelling of that substance.

28. Furthermore, Article 112 of the Act concerning the conditions of accession of the Republic of Austria, the Republic of

6 — OJ, English Special Edition 1967, p. 234.

7 — Articles 30 and 31 of the classification directive were introduced by Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548 (OJ 1992 L 154, p. 1).

Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded,[8] read together with the provisions of Annex XII to that Act, laid down a transitional period of four years from the date of accession, subsequently extended to 31 December 2000 by Directive 1999/33/EC of the European Parliament and of the Council of 10 May 1999, amending Directive 67/548/EEC as regards the labelling of certain dangerous substances in Austria and Sweden,[9] during which the existing Swedish classification of trichloroethylene is to remain in force, even though it differs from the Community classification.

29. The Commission then cites Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations[10] (hereinafter 'the marketing directive'), and Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances[11] (hereinafter 'the risks evaluation regulation').

30. It submits that the classification and marketing directives, together with the risks evaluation regulation, create a set of Community rules on trichloroethylene which is commensurate with stringent requirements and is sufficiently well developed to render any national prohibition on the use of trichloroethylene superfluous or disproportionate.

31. In its view, it is clear from the judgment of 14 October 1987 in *Commission* v *Denmark*[12] that the Community legislature has laid down an exhaustive set of rules governing the notification, classification, packaging and labelling of dangerous substances and that it has not left the Member States any scope to introduce other measures in their national legislation. Trichloroethylene is classified as a carcinogen in the least dangerous category, a classification that is subject to requirements in respect of safety and the protection of workers.

32. The Swedish Government points out that there are at present no Community provisions harmonising the use of trichloroethylene.

33. The question is therefore whether the harmonisation introduced with regard to

8 — OJ 1994 C 241, p. 21 and OJ 1995 L 1, p. 1.
9 — OJ 1999 L 199, p. 57.
10 — OJ 1976 L 262, p. 201.
11 — OJ 1993 L 84, p. 1.
12 — Case 278/85 [1987] ECR 4069.

dangerous substances has any bearing on the right of Member States to prohibit the use of trichloroethylene for industrial purposes.

34. The Court has consistently held that although Article 36 of the EC Treaty (now, after amendment, Article 30 EC) allows the maintenance of restrictions on the free movement of goods, justified on grounds which constitute a fundamental requirement recognised by Community law, recourse to Article 36 is no longer possible where Community directives provide for harmonisation of the measures necessary to achieve the specific objective which would be furthered by reliance upon that provision. [13]

35. Is that the case in this instance?

36. It can be inferred from Opinion 2/91 [14] that the classification directive contains rules which are more than minimum requirements and that the Community has sole jurisdiction in the field covered by that directive.

37. However, the exhaustive provisions of the classification directive cover a very clearly defined area, namely the notification, classification, packaging and labelling of dangerous substances. As regards the use of such substances, the classification directive merely requires that their packaging bear safety recommendations designed to inform the public of the particular care that should be taken when handling the substances in question.

38. That directive does not harmonise the conditions under which dangerous substances may be marketed or used in the manufacturing process.

39. On the other hand, the marketing directive determines whether it is necessary to place certain restrictions on the marketing or use of dangerous substances and preparations and requires Member States to take all necessary measures to ensure that the dangerous substances and preparations listed in the Annex to the directive may only be placed on the market or used subject to the conditions specified therein.

40. It is not disputed that trichloroethylene is not among the dangerous substances and

13 — See Case C-5/94 *Hedley Lomas* [1996] ECR I-2553, paragraph 18, Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraph 5, Case 247/84 *Motte* [1985] ECR 3887, paragraph 11 and Case 304/84 *Muller and Others* [1986] ECR 1511, paragraph 14.

14 — Opinion 2/91 [1993] ECR I-1061 (paragraph 22 et seq.) on Convention No 170 of the International Labour Organisation concerning safety in the use of chemicals at work.

preparations listed in the Annex to the marketing directive.

41. Does it therefore follow that the marketing directive precludes national legislation imposing restrictions on the use of trichloroethylene?

42. The elements of a reply to that question may be inferred from the judgment in *Burstein*,[15] which prefigures the present case in that the Court was asked to interpret the marketing directive in a similar case concerning pentachlorophenol (hereinafter 'PCP').

43. In that case, the Court noted, first, that the original version of the Annex to the marketing directive made no mention of PCP, its salts and esters, and second, that in 1989 the Federal Republic of Germany adopted a regulation prohibiting PCP and in particular the marketing or use for commercial or industrial purposes of products which, as a result of treatment with PCP, contain that substance in a concentration of more than 5 mg/kg.

44. In 1991, the Council adopted Directive 91/173/EEC of 21 March 1991 amending for the ninth time Directive 76/769,[16] which modified the marketing directive by introducing rules relating to PCP. Member States were required to bring into force the laws, regulations and administrative provisions necessary to comply with the directive before 1 July 1992. That directive provided that, with some exceptions, PCP, its salts and esters were not to be used in a concentration equal to or greater than 0.1% by mass in substances or preparations placed on the market. However, the Federal Republic of Germany continued to apply its more stringent national provision. The national court asked in essence, whether the limit value established in Annex I to the marketing directive, as amended by Directive 91/173, was applicable only to PCP, its salts and esters and to preparations produced from those substances, or whether that limit also applied to products treated with those substances or preparations.

45. The Court held that in the absence of provisions to the contrary, the restrictions laid down by the marketing directive, as amended by Directive 91/173, do not apply to products treated with such substances or preparations,[17] notwithstanding the fact that those substances are listed in the Annex to the Directive, 'with the result that the Member States remain in principle

15 — Case C-127/97 [1998] ECR I-6005.

16 — OJ 1991 L 85, p. 34.

17 — See judgment in *Burstein* cited above, paragraphs 24 and 31.

free to fix limit values for such products independently.'

46. It is apparent from that judgment that the marketing directive does no more than state certain minimum requirements. It therefore presents no obstacle to the regulation by the Member States of the marketing of substances that do not fall within its scope, provided — needless to say — that they comply with the rules of the Treaty when exercising such a power.

47. Nor, finally, does the risks evaluation regulation preclude the Member States from exercising such a power. Its objective is to establish a procedure for evaluating the risks associated with existing substances and identifying priority substances which, because of their potential effects on man and the environment, require immediate attention at Community level. It is intended to assist in the management of such risks at Community level. [18] However, the risks evaluation regulation does not impose obligations with regard to the use of those substances in general and trichloroethylene in particular. Under Article 11(3) of that regulation, it is for the Commission, where appropriate, to propose Community measures within the framework of either the marketing directive or another appropriate Community instrument on the basis of the results of a risks evaluation carried out and strategy recommended in accordance with that regulation.

48. In the light of these considerations, I therefore take the view that the classification directive, the marketing directive and the risks evaluation regulation, jointly or separately, preclude the national legislation at issue.

B — *Appraisal in relation to Article 30 of the EC Treaty (now, after amendment, Article 28 EC) and Article 36 of the Treaty*

49. The Swedish Government maintains that, according to the case-law of the Court, in particular the judgments in

18 — See Article 1(1)(b).

Frans-Nederlandse Maatschappij voor Biologische Producten,[19] *Sandoz*[20] and *Brandsma*,[21] in the absence of harmonisation, it is for the Member States to decide what degree of protection of the health and life of humans they intend to assure, having regard however for the requirements of the free movement of goods. It considers that Member States should be allowed a wide margin of discretion in that regard.

50. The Commission acknowledges that in the absence of any Community rule governing trichloroethylene, the Member States are free to determine independently the degree of protection that is to apply, provided always that the protective measures are necessary and proportionate.

51. The Commission argues that the Swedish law could have a restrictive effect on trade between Member States. Furthermore, since trichloroethylene is not produced in Sweden, it constitutes an obstacle to the free movement of goods.

52. The parties agree that the Swedish legislation constitutes a measure having an effect equivalent to a quantitative restriction within the meaning of Article 30 of the Treaty.

53. According to the wording of the judgment in *Dassonville*,[22] 'all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade' are to be considered as measures having an effect equivalent to quantitative restrictions.

54. The legislation at issue is likely to bring about a reduction in the volume of trichloroethylene imported, as it is designed to stop the use of trichloroethylene in the manufacturing process, which effectively restricts, if not suspends, its importation into Sweden. Although exemptions may be granted, it is clear from the written observations and from the submissions made at the hearing that they will be merely temporary and short-term and that the long-

19 — Case 272/80 [1981] ECR 3277.
20 — Case 174/82 [1983] ECR 2445.
21 — Case C-293/94 [1996] ECR I-3159.
22 — Case 8/74 [1974] ECR 837.

term objective of the Swedish legislature is unchanged.

55. The question therefore arises as to whether that legislation can be justified under Article 36 of the Treaty.

56. Article 36 of the Treaty remains applicable as long as harmonisation of national legislation has not been fully achieved. [23]

57. Article 36 permits national laws to derogate from the principle of the free movement of goods to the extent to which such derogation is and continues to be justified for the attainment of the objectives referred to in that article. [24] Those objectives preclude the protection of health and life of humans, animals or plants. In accordance with the second sentence of Article 36 of the Treaty, prohibitions or restrictions must not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

58. National measures must be proportionate in relation to the objective to be achieved, in other words they must be necessary for the effective protection of health and life of humans and the environment and must hinder the free movement of goods as little as possible. It must not be possible to achieve that objective by measures which are less restrictive. [25]

59. The Swedish Government explains that on the basis of the scientific data available in the 1980s, in 1988 trichloroethylene was classified as harmful and carcinogenic in category carc. cat III R40 under the classification directive.

60. The following definition applies to that category: 'substances which are of concern to humans because of their possible carcinogenic effects, but which cannot be satisfactorily evaluated on the basis of the information available. There is information from appropriate animal studies but this is

23 — See Case 215/87 *Schumacher* [1989] ECR 617, paragraph 15, Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 48, Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, paragraph 26, Case C-62/90 *Commission* v *Germany* [1992] ECR I-2575, paragraph 10, Case C-317/92 *Commission* v *Germany* [1994] ECR I-2039, paragraph 14, and Case C-320/93 *Ortscheit* [1994] ECR I-5243, paragraph 14. See also the judgments in *Motte*, paragraph 16, and *Muller and Others*, paragraph 14, cited above and Case C-42/90 *Bellon* [1990] ECR I-4863, paragraph 10.

24 — See, in particular, Case 35/76 *Simmenthal* [1976] ECR 1871, paragraph 14, and Case 5/77 *Tedeschi* [1977] ECR 1555, paragraph 34.

25 — See judgments in Case C-62/90 *Commission* v *Germany*, cited above, paragraphs 10 and 11, and Case C-320/93 *Ortscheit*, cited above, paragraphs 16 and 17.

insufficient to classify the substance in the second category.'

61. The Swedish Government adds that in 1996 trichloroethylene was given an 'R52/53' risk factor, indicating that the substance is 'harmful to aquatic organisms' and that it 'may cause long-term effects on the aquatic environment.'

62. The Swedish Government also submits that, in recent years, concern has been mounting. In particular, the International Cancer Research Agency, set up by the World Health Organisation, has produced evidence — to a limited extent from epidemiological tests carried out on people, and more fully from experiments carried out on animals — that trichloroethylene is a carcinogen. Trichloroethylene is currently being assessed for risks under the procedure introduced by the risks evaluation regulation. Most scientific experts in the Member States consider that there should be a more stringent classification of trichloroethylene. However, the committee chaired by the Commission has been unable to reach agreement on an evaluation.

63. The Swedish Government adds that a threshold for the carcinogenic effect of trichloroethylene in humans has not been, or cannot be, established. Trichloroethylene affects the central nervous system, the liver and kidneys and the fact that it is highly volatile increases the chances of exposure in circumstances that might result in damage to health. Inhaling the substance can cause fatigue, headaches and difficulties with memory and concentration.

64. It points out that the legislation is part of a government programme to prevent discharges of trichloroethylene. The legislation is justified within the meaning of Article 36 of the Treaty, as it is necessary to prohibit the use of trichloroethylene for industrial purposes in order to achieve the objective of the programme. Its aim is to reduce as far as possible the risks connected with the use of trichloroethylene, particularly those associated with the use of trichloroethylene for degreasing and drying in the manufacture of machinery, without burdening undertakings with requirements beyond what is reasonable in each case. Moreover, the prohibition is not absolute, since exemptions are granted provided that the use of the substance does not entail unacceptable exposure and that there is no acceptable alternative solution. The objective of the programme could be achieved only by means of individual authorisation taking into account the specific nature of each case and enabling the actual use of the product to be verified and controlled, with a view to finding an alternative solution.

65. The legislation does not therefore go beyond what is necessary in the light of the interests to be protected. Moreover, it is effective because since the prohibition on using trichloroethylene was introduced, the number of users has decreased and alternative solutions which are less harmful to health and the environment have been found.

66. Conversely, the Commission contends that the prohibition on the use of trichloroethylene cannot be justified under Article 36 of the Treaty. There are, it claims, less stringent ways of achieving the desired objective. A Member State wishing to give a higher degree of protection to its workers and environment than that afforded under Community law could, for example, impose a limit on the exposure time.

67. Article 36 of the Treaty also precludes the exemptions provided for under the Swedish legislation, as the criteria for granting authorisation for use are not sufficiently objective and give the administration a very wide discretion. The criteria could be described as objective only if the authorisation for use were subject to a restriction on exposure time or maximum levels of emission.

68. At the hearing, the Swedish Government pointed out, without being challenged by the other parties, that there are national rules limiting the exposure of workers to trichloroethylene. They are taken into account when requests for exemption are assessed. By way of example, the Swedish Government cites the recommendations contained in directive AFS, 96/2, on the protection of workers, which stipulate, amongst other things, that the employer must ensure that the average exposure during a 15-minute period does not exceed 22 ppm or 40 mg/m^3. In any event, the Swedish legislation also seeks to achieve a long-term objective by introducing the principle of substitution by which dangerous substances are to be replaced by less dangerous ones.

69. What are the merits of these various arguments?

70. I note, first, that there is no suggestion that the Swedish legislation is based on considerations other than the protection of health and life of humans or protection of the environment. It also follows from the classification of trichloroethylene on the basis of the relevant directive that the dangerous nature of that product is genuine

and is acknowledged at Community level. The possibility that the Swedish legislation is introducing a means of arbitrary discrimination or a disguised restriction on trade between Member States under the pretext of a rule to protect interests recognised by Article 36 of the Treaty can therefore be ruled out.

71. The case-law relating to the justification of national measures under Article 36 of the Treaty on grounds of public health is particularly abundant.

72. Thus, on the use of food additives, the Court held in *Koninklijke Kaasfabriek Eyssen*,[26] that whilst a national provision prohibiting the use of a particular food additive has the effect of hindering trade between Member States, it may be justified under Article 36 of the Treaty on the ground of the protection of human health, especially in view of the difficulties in establishing the critical threshold beyond which the intake of that additive would constitute a serious risk to human health.

73. That judgment confirms that there are specific cases where even a total ban on using a harmful substance may be justified under Article 36 of the Treaty.

74. There is all the more reason for that to be so in the case of a prohibition on use coupled with a system of exemptions, if the conditions for granting exemption also fulfil the proportionality requirement laid down in Article 36 of the Treaty.

75. It should be remembered that, prior to 1 April 1997, these exemptions were granted subject to four conditions: the absence of a less dangerous alternative product, the obligation on the applicant to seek an alternative solution which is less harmful to public health and the environment, the absence of instances of unacceptable exposure to trichloroethylene and the notification of a plan indicating, in particular, when and how the trichloroethylene was to be replaced.

76. Exemptions were granted, in accordance with Article 3(2) of the regulation, on payment of an administrative fee, as provided for in paragraph 19 of Law 1985:426.

26 — Case 53/80 [1981] ECR 409.

77. Let us now examine these conditions in the light of the requirements of the principle of proportionality.

78. The Swedish Government has dwelt at length on the reasons which led the Swedish legislature to draw up the legislation at issue which was based on what the Swedish Government called the 'principle of substitution', the idea being that the use of trichloroethylene for industrial purposes is to be gradually but completely abolished, by substituting less harmful products.

79. Toolex is the only party which challenges the principle underlying the legislation at issue. It wonders why the Swedish Government chose that particular substance and complains of the costs to Swedish undertakings and their loss of competitiveness compared with companies established in Member States where there is free use of trichloroethylene.

80. The Swedish Government invokes four directives in support of its argument, namely Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work,[27] Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC),[28] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers against the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC),[29] and Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations.[30]

81. None of those directives applies to the present case, though all of them require the employer to introduce measures for the protection of workers, on the basis of general principles of prevention including avoiding or reducing risks and replacing the dangerous by the less dangerous substance.

82. The principle of substitution is therefore not unknown to Community law and

27 — OJ 1989 L 183, p. 1, see Article 6(2)(f).
28 — OJ 1990 L 196, p. 1, see Articles 4 and 5.
29 — OJ 1998 L 131, p. 11, see Article 6(2).
30 — OJ 1999 L 85, p. 1.

it is therefore difficult to see why, where there is an established risk to health and the environment, a national legislature, within the framework of Article 36 of the Treaty, should be precluded from basing its legislation on a principle recognised by Community law.

83. In that context, I would add that the Court has consistently held that it is for the national authorities to demonstrate that their legislation is justified on grounds relating to the protection of the health of their population [31] and that the risk to health must be assessed with due regard to the results of international scientific research. [32]

84. Without entering into a detailed analysis of the scientific papers produced by the Swedish Government, suffice it to say that trichloroethylene has been found to be a danger to health and the environment at Community level. None of the parties dispute that. They differ only on the degree of danger posed by that substance.

85. Although the Commission argues that the Swedish legislation goes beyond what is necessary to achieve the desired objective of protecting health, and that the Swedish legislature could have merely imposed limit values on exposure to trichloroethylene, it has been unable to produce any scientific evidence to contradict the Swedish Government's assertion that the limits of toxicity of trichloroethylene are unknown.

86. Therefore, merely to set limit values would not be a satisfactory solution to the problems posed by the use of trichloroethylene.

87. It cannot therefore be maintained that to make the granting of exemption subject to a requirement that the applicant seek an alternative solution or to refuse to grant exemption if there is an alternative product that is less dangerous, would be disproportionate in relation to the objectives pursued by Article 36 of the Treaty.

88. Furthermore, according to settled case-law, 'in so far as there are uncertainties in the present state of scientific research, it is for the Member States, in the absence of

31 — See, in particular, Joined Cases C-13/91 and C-113/91 *Debus* [1992] ECR I-3617, paragraph 18, and the case-law cited therein.

32 — See, in particular, the judgments in *Muller and Others*, cited above, paragraph 26, *Bellon*, cited above, paragraphs 16 and 17, and Case C-344/90 *Commission* v *France* [1992] ECR I-4719, paragraphs 9 and 10.

harmonisation, to decide what degree of protection of the health and life of humans they intend to assure, having regard, however, to the requirements of the free movement of goods within the Community.' [33]

89. The Commission also contends that the legislation at issue contains criteria that are not objective and that leave the administrative authority free to make an arbitrary assessment.

90. The criteria for granting authorisation to use trichloroethylene must be evaluated in the light of the principles which can be deduced from the judgments in *Motte*, *Muller and Others* and *Bellon*, [34] cited above, which, although delivered in cases concerning the use of a food additive, have in my view a more general scope.

91. It follows from those judgments that the principle of proportionality requires that the procedure for issuing prior administrative authorisation must be readily accessible to traders. It must be completed within a reasonable time and, if it leads to a rejection by the competent administrative authorities, that rejection must be open to challenge before the courts. [35]

92. In the present case, as the Swedish Government confirmed at the hearing, even if the applications are assessed case by case — which, *per se*, in no way means that the assessment is arbitrary, — the administrative authorities monitor, in particular, compliance with the condition prohibiting unacceptable exposure to trichloroethylene in relation to the predetermined limit values for exposure.

93. Furthermore, rejection of an application for authorisation can be challenged before the courts.

94. Moreover, the Swedish Government points out that all the applications for exemption made on the basis of the new provisions have been accepted and that 150 undertakings are at present authorised to use trichloroethylene.

33 — See, in particular, the judgments in *Bellon*, cited above; Case 97/83 *Melkunie* [1984] ECR 2367, paragraph 18, and Case C-375/90 *Commission* v *Greece* [1993] ECR I-2055, paragraph 19.

34 — See the judgments in *Motte*, cited above, paragraph 25, *Muller and Others*, cited above, paragraph 26, *Bellon*, cited above, paragraphs 16 and 17 and *Commission* v *France*, cited above, paragraphs 9 and 10.

35 — See also judgments in Case 222/86 *Heylens and Others* [1987] ECR 4097, paragraphs 14 to 17, Case C-340/89 *Vlassopoulou* [1991] ECR I-2357, paragraph 22, and Case C-19/92 *Kraus* [1993] ECR I-1663, paragraph 41.

95. The Commission's allegation is therefore unfounded.

96. On the other hand, to require, as the Chemicals Inspectorate did in the case of applications submitted before 1 April 1997, that the applicant draw up a plan indicating when the use of trichloroethylene will be discontinued, was to impose a disproportionate condition. Since it is extremely difficult to predict scientific and technical progress, that condition would render the granting of exemption virtually impossible in many cases. It was also superfluous, as it contributed nothing to the achievement of the desired objectives. Moreover, when the existing administrative practice was codified, the Swedish legislature waived that requirement.

97. The Commission and Toolex also complain that the Swedish legislature makes the granting of exemption subject to payment of an administrative fee, which, according to the information provided, was SEK 1 000 for undertakings which had reported temporary difficulties and SEK 2 500 for undertakings which had made a valid application for authorisation after the transitional period.

98. If that complaint is to be understood as an objection to any charge for granting an individual exemption, it is unfounded.

99. In its abundant case-law on the conditions under which a Member State may rely on Article 36 of the Treaty to justify measures which restrict the free movement of goods, the Court has never asserted that where a set of rules prohibiting the use of an imported product is admissible under Articles 30 and 36 of the Treaty only because it entitles traders to seek individual exemption, those exemptions must be issued free of charge.

100. On the other hand, if it is to be understood as an objection to the amount of the fees charged for granting exemption, it may rely on the case-law of the Court which has always held that procedures for obtaining exemption must be easily accessible and therefore that the charges to traders must not be so high as to discourage them from applying for exemption and must not, in any event, be fixed arbitrarily. [36]

101. However, the question whether, in the present case, the amounts laid down by the Swedish legislation meet the Court's requirements is a matter for the national court to decide.

36 — See, in particular, Case 54/85 *Mirepoix* [1986] ECR 1067, paragraph 16 and Case 406/85 *Gofette and Gilliard* [1987] ECR 2525, paragraph 10.

IV — Conclusion

102. In the light of the foregoing considerations, I propose that the Court reply to the question referred by the Kammarrätten i Stockholm to the effect that Articles 30 (now, after amendment, Article 28 EC) and 36 (now, after amendment, Article 30 EC) of the EC Treaty must be interpreted as meaning that they do not preclude a Member State from prohibiting the use of trichloroethylene for industrial purposes in its territory and making the granting of individual exemption subject to three conditions: the obligation to seek an alternative solution which is less harmful to the environment and public health; the absence of such an alternative solution at present; and the absence of instances of unacceptable exposure to the substance, provided that such exemption can be obtained through a readily accessible procedure, that it does not depend on the payment of excessive administrative fees and that rejection of an application for exemption may be challenged before the courts.