JUDGMENT OF THE COURT

11 July 2000 *

In Case C-473/98,

REFERENCE to the Court under Article 177 of the EC Treaty (now Article 234 EC) by the Kammarrätten i Stockholm (Sweden) for a preliminary ruling in the proceedings pending before that court between

Kemikalieinspektionen

and

Toolex Alpha AB

on the interpretation of Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC),

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, J.C. Moitinho de Almeida, D.A.O. Edward, L. Sevón, R. Schintgen (Presidents of Chambers), J.-P. Puisso-

* Language of the case: Swedish.

chet, G. Hirsch, P. Jann, H. Ragnemalm, M. Wathelet (Rapporteur) and F. Macken, Judges,

Advocate General: J. Mischo,
Registrar: L. Hewlett, Administrator,

after considering the written observations submitted on behalf of:

— Kemikalieinspektionen, by L. Lindström, of the Stockholm Bar, and C.M. von Quitzow,

— Toolex Alpha AB, by H. Lindberg,

— the Swedish Government, by L. Nordling, Rättschef in the Ministry of Foreign Affairs, and A. Kruse, Departementsråd in the same Ministry, acting as Agents,

— the Commission of the European Communities, by L. Ström, Legal Adviser, acting as Agent,

having regard to the Report for the Hearing,

after hearing the oral observations of Toolex Alpha AB, of the Swedish Government and of the Commission at the hearing on 8 February 2000,

after hearing the Opinion of the Advocate General at the sitting on 21 March 2000,

gives the following

Judgment

1 By order of 17 December 1998, received at the Court on 21 December 1998, the Kammarrätten i Stockholm (Administrative Court of Appeal, Stockholm) referred to the Court for a preliminary ruling under Article 177 of the EC Treaty (now Article 234 EC) a question on the interpretation of Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC).

2 That question was raised in proceedings between Kemikalieinspektionen (the Swedish Chemicals Inspectorate) and Toolex Alpha AB (hereinafter 'Toolex') concerning the latter's right to use trichloroethylene in industrial processes.

The Community legislation

3 The relevant Community legislation is composed of the following:

— 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 (OJ, English Special Edition 1967, p. 234, hereinafter 'the classification directive');

— 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 (OJ 1976 L 262, p. 201, hereinafter 'the marketing directive');

— Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ 1993 L 84, p. 1, hereinafter 'the risks evaluation regulation').

4 The objectives of the classification directive are twofold: to protect the population, and in particular workers who use dangerous substances and preparations (the first recital), and to remove barriers to trade in those substances and preparations (the second recital). The directive, which has frequently been amended, lays down general principles governing the classification, packaging and labelling of dangerous substances and preparations, and leaves to subsequent directives the task of harmonising provisions relating to the use of dangerous substances and preparations (the fifth recital).

5 Trichloroethylene is classified as a category 3 carcinogen, with the indications R 40 (toxic) and R 52/53 (harmful to the environment). Carcinogens are divided into three categories, category 3 containing the least dangerous of them. R 40 indicates 'possible risks of irreversible effects' and R 53 that the substance 'may cause long-term adverse effects in the aquatic environment'.

6 Article 112 of the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties upon which the European Union is founded (OJ 1994 C 241, p. 21 and OJ 1995 L 1, p. 1), 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 (OJ 1999 L 199, p. 57), during which the existing Swedish classification of trichloroethylene is to remain in force. Sweden uses an additional 'R' indication not specified in the Community classification scheme.

7 The marketing directive imposes restrictions on the marketing and use of dangerous substances and preparations. Article 2 of the directive provides that:

'Member States shall take all necessary measures to ensure that the dangerous substances and preparations listed in the Annex may only be placed on the market or used subject to the conditions specified therein ...'.

8 Trichloroethylene does not appear in the list of dangerous substances and preparations given in the Annex.

9 Article 8(1) of the risks evaluation regulation provides that, on the basis of the information submitted by manufacturers and importers in accordance with Articles 3 and 4 of that regulation, and on the basis of the national lists of priority substances, the Commission, in consultation with the Member States, is regularly

to draw up lists of priority substances or groups of substances requiring immediate attention because of their potential effects on man or the environment.

10 Article 10(1) of the risks evaluation regulation provides that, for each substance on the priority lists, responsibility for its evaluation is to be given to a Member State, which must designate a rapporteur for the substance from among the competent authorities referred to in Article 13.

11 On the basis of the risks evaluation and strategy for limiting those risks recommended by the rapporteur, the Commission will decide, where necessary, to propose Community measures in the framework of the marketing directive or in the framework of other appropriate Community instruments (Article 11 of the risks evaluation regulation).

12 Trichloroethylene underwent a risks evaluation pursuant to the risks evaluation regulation. According to that evaluation it is appropriate to limit the risks to which workers and consumers are exposed, and to which the population in general is exposed, from the environment. An evaluation of the risks to the environment also led to the finding that there is a possibility of contamination of plant-life. A strategy for reducing those risks is currently being prepared.

The national legislation

13 The lagen (1985:426) om kemiska produkter (Swedish Law on chemical products) enables the Swedish Government, or the administrative authority appointed by it, to prohibit the treatment, import or export of a chemical product if there are specific health or environmental protection reasons for doing so.

14 In the exercise of that power, the Swedish Government enacted the förordningen (1991:1289) om vissa klorerade lösningsmedel (Swedish regulation on certain chlorinated solvents). Article 2 of that regulation prohibits the sale, transfer or use, for industrial purposes, of chemical products composed wholly or partially of trichloroethylene. That ban came into force on 1 January 1996.

15 However, Article 3 of the same regulation enables the Chemicals Inspectorate to grant general exemptions where they are justified on specific grounds, and individual exemptions where there are 'special' reasons for doing so.

16 On the basis of that provision, the Chemicals Inspectorate adopted the Kemikalieinspektionens föreskrifter om undantag från förbud i förordningen (1991:1289) om vissa klorerade lösningsmedel, KIFS 1995:6 (the Chemical Inspectorate's rules on exemptions from the prohibitions contained in Regulation 1991:1289 on certain chlorinated solvents, hereinafter 'KIFS 1995:6'), which also came into force on 1 January 1996.

17 Under Article 4 of KIFS 1995:6 undertakings experiencing temporary difficulties were allowed to use trichloroethylene for degreasing and drying until the end of 1996, subject to certain conditions. In particular, 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. In addition, 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 how the applicant proposed to resolve them, and state the time it presumed it would take to resolve those difficulties.

18 Article 5 of KIFS 1995:6 provided that the Chemicals Inspectorate 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.

19 KIFS 1995:6 was amended in 1996 and 1997 by KIFS 1996:8 and 1997:3 respectively, and was subsequently replaced by KIFS 1998:8, Section 4, Chapter 9.

20 Following the 1996 amendment of KIFS 1995:6, 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 using trichloroethylene for degreasing and drying until 31 March 1997.

21 KIFS 1997:3, which came into force on 1 April 1997, inserted a new Article 1a into KIFS 1995:6. Under that provision, 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.'

On the other hand, the Chemicals Inspectorate 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.

The main proceedings

22 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. Like another 220 or so undertakings, it applied for permission to continue using trichloroethylene after March 1997.

23 By decision of 18 June 1996 the Chemicals Inspectorate rejected Toolex's application, essentially on the ground that, like 90% or so of the applicant undertakings, it was unable to submit a plan for discontinuing its use of trichloroethylene. Toolex brought an action before the Länsrätten i Stockholm Län (County Administrative Court, Stockholm), which annulled the Chemicals Inspectorate's decision on the ground that the Swedish legislation relating to the matter was inconsistent with Community law.

24 The Chemicals Inspectorate appealed that decision before the Kammarrätten i Stockholm, which referred the following question to the Court of Justice for a preliminary ruling:

'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 EC Treaty?'

Preliminary observations

25 It should be observed at the outset that, whilst Article 36 of the Treaty allows the maintenance of national restrictions on the free movement of goods, justified on grounds which constitute fundamental requirements recognised by Community law, recourse to Article 36 is not 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 (see, to that effect, Case C-5/94 *Hedley Lomas* [1996] ECR I-2553, paragraph 18).

26 Thus, before answering the question referred by the national court concerning the interpretation of Articles 30 and 36 of the Treaty, it is necessary first to establish whether the Member States are still entitled to regulate the industrial use of trichloroethylene, in view of the secondary legislation referred to in paragraphs 3 to 12 of the present judgment.

The scope of the Community legislation

27 The Commission 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 safety requirements and is sufficiently well developed to render any national prohibition on the use of the substance superfluous.

28 The Court does not share that view.

29 The classification directive covers a very clearly defined field, 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 general public of the particular care that should be taken when handling the substance in question. It does not harmonise the conditions under which dangerous substances may be marketed or used, which are the very matters that fall within the purview of national legislation such as that in issue in the main proceedings.

30 Given that the marketing directive, in itself, does no more than state certain minimum requirements, as is plain from Article 2 thereof, mentioned in paragraph 7 of the present judgment, it clearly presents no obstacle to the regulation by the Member States of the marketing of substances that do not fall within its scope, such as trichloroethylene.

31 Nor, finally, does the risks evaluation regulation, in itself, 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. Although it is intended to assist in the management of such risks at Community level, the risks evaluation regulation neither imposes obligations nor harmonises rules on the use of substances in general or trichloroethylene in particular.

32 Whilst, under Article 11(3) of the risks evaluation regulation, it is for the Commission 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, the fact remains that it has not yet exercised that power with regard to trichloroethylene.

33 Given that secondary Community law does not therefore prevent a Member State from regulating the industrial use of trichloroethylene, it is necessary to consider the question concerning the interpretation of Articles 30 and 36 of the Treaty.

Articles 30 and 36 of the Treaty

34 By its question the national court is essentially asking whether Articles 30 and 36 of the Treaty are to be interpreted as precluding any national rules which include a general prohibition on the industrial use of trichloroethylene and establish a system of individual exemptions.

35 It should first be observed that national legislation such as that at issue in the case in the main proceedings constitutes, in principle, a measure having an effect equivalent to a quantitative restriction within the meaning of Article 30 of the Treaty.

36 On the one hand, the general prohibition on the industrial use of trichloroethylene is likely to bring about a reduction in the volume of trichloroethylene imported.

37 On the other hand, although individual exemptions may be granted by the competent national authority, the concept of a measure having an effect

equivalent to a quantitative restriction also applies to the obligation imposed upon economic operators to apply for exemption or a dispensation from a national measure which itself amounts to a quantitative restriction or measure having equivalent effect (see, *inter alia*, Case 82/77 *Van Tiggele* [1978] ECR 25, paragraph 19, and Case 251/78 *Denkavit Futtermittel* [1979] ECR 3369, paragraph 11). Moreover, it is clear from the written obervations and from the submissions made at the hearing that any exemptions granted are merely temporary and that the long-term objective of the Swedish legislature is still to remove trichloroethylene from industrial use entirely.

38 Second, it should be borne in mind that the health and life of humans rank foremost among the property or interests protected by Article 36 of the Treaty (Case C-320/93 *Ortscheit* [1994] ECR I-5243, paragraph 16).

39 On this point there has been no suggestion that national legislation, such as that in issue in the case in the main proceedings, which aims to prohibit absolutely the industrial use of trichloroethylene, might be based upon any considerations other than the protection of the health and life of humans or the protection of the environment. Moreover, it is clear from the classification of trichloroethylene under the classification directive that it is acknowledged at Community level that the substance is dangerous.

40 However, national rules or practices having, or likely to have, a restrictive effect on the importation of products are compatible with the Treaty only to the extent that they are necessary for the effective protection of the health and life of humans. A national rule or practice cannot therefore benefit from the derogation provided for in Article 36 of the Treaty if the health and life of humans may be protected just as effectively by measures which are less restrictive of intra-Community trade (see, in relation to pharmaceuticals, Case 215/87 *Schumacher*

[1989] ECR 617, paragraph 18, Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 53, Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, paragraph 27, and *Ortscheit*, cited above, paragraph 17).

41 The Swedish Government submits that trichloroethylene affects the central nervous system, the liver and kidneys. 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.

42 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.

43 Following the International Cancer Research Agency's investigations, which were carried out in 1995, other epidemiological studies were published concerning the link between exposure to trichloroethylene and the incidence of cancer in humans. A recent German case-study produced statistics indicating a link between the incidence of renal cancer and exposure to trichloroethylene. Those results corroborated the findings set out in an earlier study, published in 1995, which also concluded that trichlorethylene can cause renal cancer in humans. Furthermore, a new American epidemiological study indicates that there is an aggravated risk of renal cancer, in particular following exposure to trichloroethylene at the workplace.

44 In addition, there is hard evidence that the carcinogenic effect of trichloroethylene upon the kidneys of a rat also occurs in humans. The toxic metabolic waste

matter and mutagens found in laboratory animals have also been identified in humans, again reinforcing suspicions that trichloroethylene can cause cancer in humans.

45 Taking account of the latest medical research on the subject, and also the difficulty of establishing the threshold above which exposure to trichloroethylene poses a serious health risk to humans, given the present state of the research, there is no evidence in this case to justify a conclusion by the Court that national legislation such as that at issue in the case in the main proceedings goes beyond what is necessary to achieve the objective in view (see, to that effect, Joined Cases 266/87 and 267/87 *Association of Pharmaceutical Importers* [1989] ECR 1295, paragraph 22).

46 In particular, the system of individual exemptions, granted subject to conditions, established by the Swedish regulation appears to be appropriate and proportionate in that it offers increased protection for workers, whilst at the same time taking account of the undertakings' requirements in the matter of continuity.

47 First, exemption is granted on condition that no safer replacement product is available and provided that the applicant continues to seek alternative solutions which are less harmful to public health and the environment. Those requirements are compatible with the 'substitution' principle which emerges, *inter alia*, from 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 (OJ 1989 L 183, p. 1) and 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) (OJ 1990 L 196, p. 1) and which consists in the elimination or reduction of

risks by means of replacing one dangerous substance with another, less dangerous substance.

48 Second, the concern to avoid causing disruption to an undertaking where there is no alternative solution does not justify the grant of an exemption unless exposure to trichloroethylene is at acceptable levels.

49 In light of the foregoing considerations, national legislation which lays down a general prohibition on the use of trichloroethylene for industrial purposes and establishes a system of individual exemptions, granted subject to conditions, is justified under Article 36 of the Treaty on grounds of the protection of health of humans.

Costs

50 The costs incurred by the Swedish Government and by the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the question referred to it by the Kammarrätten i Stockholm by order of 17 December 1998, hereby rules:

National legislation which lays down a general prohibition on the use of trichloroethylene for industrial purposes and establishes a system of individual exemptions, granted subject to conditions, is justified under Article 36 of the EC Treaty (now, after amendment, Article 30 EC) on grounds of the protection of health of humans.

Rodríguez Iglesias Moitinho de Almeida Edward

Sevón Schintgen Puissochet

Hirsch Jann Ragnemalm

Wathelet Macken

Delivered in open court in Luxembourg on 11 July 2000.

R. Grass G.C. Rodríguez Iglesias

Registrar President