ORDER OF THE PRESIDENT OF THE COURT OF FIRST INSTANCE

10 February 2005 *

In Case T-291/04 R,

Enviro Tech Europe Ltd, established in Surrey (United Kingdom),

Enviro Tech International, Inc., established in Chicago, Illinois (United States),

represented by C. Mereu and K. Van Maldegem, lawyers,

applicants,

v

Commission of the European Communities, represented by X. Lewis and D. Recchia, acting as Agents, with an address for service in Luxembourg,

defendant,

* Language of the case: English.

APPLICATION for, first, suspension of the inclusion of n-propyl-bromide in Commission Directive 2004/73/EC of 29 April 2004, adapting to technical progress for the 29th time 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 2004 L 152, p. 1) and, second, further interim measures,

THE PRESIDENT OF THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES,

makes the following

Order

Legal framework

General legal framework

1 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), as amended by Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548 (OJ 1992 L 154, p. 1), lays down rules concerning the marketing of certain 'substances', defined as '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'.

2 Directive 67/548 has been amended several times since its adoption and, most recently, by Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Council Directive 67/548 (OJ 2004 L 152, p. 1).

3 Article 4 of Directive 67/548, as amended, provides that substances are to be classified on the basis of their intrinsic properties according to the categories of danger laid down by Article 2(2). Classification of a chemical as 'dangerous' requires appropriate labelling on the package, including a danger symbol, standard phrases indicating the special risks arising from the dangers involved in using the substance ('R-phrases') and standard phrases relating to the safe use of the substance ('S-phrases').

4 Article 2(2) of Directive 67/548, as amended, provides that substances and preparations which are, inter alia, 'extremely flammable', 'highly flammable', 'flammable' or 'toxic for reproduction' are 'dangerous' within the meaning of the Directive.

5 As regards the tests which may be carried out for the purpose of classifying substances, Article 3 of Directive 67/548, as amended, provides:

'Tests on chemicals carried out within the framework of this Directive shall as a general principle be conducted according to the methods laid down in Annex V. The physico-chemical properties of substances shall be determined according to the methods specified in Annex V.A ...'.

6 Annex V, point A.9, to Directive 67/548, as amended, lays down the methods for determining flash points.

7 Article 4(2) of Directive 67/548, as amended, provides that the general principles of the classification and labelling of substances and preparations are to be applied according to the criteria set out in Annex VI, save where contrary requirements for dangerous preparations are specified in separate directives.

8 Annex VI, Point 4.2.3, to Directive 67/548, as amended, contains the criteria applicable for reproductive toxicity and divides reproductive toxicant substances into three categories:

— Category 1: 'substances known to impair fertility in humans' and 'substances known to cause developmental toxicity in humans';

— Category 2: 'substances which should be regarded as if they impair fertility in humans' and 'substances which should be regarded as if they cause developmental toxicity in humans';

— Category 3: 'substances which cause concern for human fertility' and 'substances which cause concern for humans owing to possible developmental toxic effects'.

Adaptation of Directive 67/548 to technical progress

9 Article 28 of Directive 67/548, as amended, provides:

'The amendments necessary for adapting the Annexes to technical progress shall be adopted in accordance with the procedure laid down in Article 29.'

10 In its observations, the Commission explained that, as a matter of practice, when it works on an initial draft of measures adapting Directive 67/548 to technical progress, it consults the Commission Working Group on Classification and Labelling ('the Working Group'), a group comprised of experts in toxicology and classification sent by the Member States, representatives of the chemical industry and representatives of the particular sector of the industry concerned by the products under discussion. After consulting with the Working Group, the Commission submits the draft measures to the committee established by Article 29 of Directive 67/548 ('the Regulatory Committee').

11 Article 29 of Directive 67/548, as amended by Council Regulation (EC) No 807/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (unanimity) (OJ 2003 L 122, p. 36), states:

'1. The Commission shall be assisted by a committee.

2. Where reference is made to this article, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.'

12 Article 5 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23) reads as follows:

'1. The Commission shall be assisted by a regulatory committee composed of the representatives of the Member States and chaired by the representative of the Commission.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time-limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 205(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that article. The chairman shall not vote.

3. The Commission shall, without prejudice to Article 8, adopt the measures envisaged if they are in accordance with the opinion of the committee.

...'.

Facts and procedure

13 N-propyl-bromide ('nPB') is a volatile organic solvent used inter alia for industrial cleaning.

14 Enviro Tech Europe Ltd and Enviro Tech International Inc. ('the applicants') are companies engaged solely in the production and sale of the nPB-based product 'Ensolv'. Enviro Tech Europe is the European subsidiary of Enviro Tech International, and its exclusive licensee in Europe for Ensolv.

15 Pursuant to Commission Directive 91/325/EEC of 1 March 1991 adapting to technical progress for the 12th time Council Directive 67/548 (OJ 1991 L 180, p. 1), nPB was included in Annex I to Directive 67/548 and was classified as an irritant and flammable substance.

16 At the meeting of the Working Group of 16 to 18 January 2002, the United Kingdom's Health & Safety Executive ('the HSE') proposed classifying nPB as a category 2 reproductive toxicant.

17 Subsequently, in April 2002, the HSE proposed, on the basis of the results of a new scientific test, that nPB should be classified as a highly flammable substance.

18 Since that date, the applicants have made submissions to the HSE, the European Chemical Bureau and the Working Group objecting to the proposed classification and providing scientific data and arguments in support of their position.

19 At its January 2003 meeting, the Working Group decided to recommend the classification of nPB as highly flammable and as a category 2 reproductive toxicant. After that decision was made, the applicants unsuccessfully tried to convince the Working Group to re-open its discussions on nPB.

20 On 29 August and 29 September 2003 respectively, the applicants sent two letters to the Commission requesting, inter alia, that it take such measures as necessary to correct the errors which they considered to underlie the Working Group's recommendations on nPB.

21 In two letters of 3 November 2003, the Commission informed the applicants that the arguments presented in their letters of 29 August and 29 September 2003 did not provide appropriate reasons to modify the classification of nPB recommended by the Working Group ('the Commission's responses').

22 By application registered at the Court Registry on 23 December 2003, the applicants brought an action for annulment of the Commission's responses and an action for damages.

23 Shortly after their applications were filed, the applicants were informed that the Regulatory Committee was scheduled to meet on 15 January 2004 in order to endorse the 29th adaptation of Directive 67/548 to technical progress.

24 By separate application, registered at the Court Registry on 30 December 2003, the applicants, in accordance with Articles 242 EC and 243 EC, brought an application for interim measures, by which they requested the President of the Court of First Instance to suspend the operation of the Commission's responses and to order the Commission not to propose the reclassification of nPB under the 29th adaptation to technical progress of Directive 67/548 at the next Regulatory Committee meeting, scheduled for 15 January 2004.

25 An order made on 3 February 2004 by the President of the Court of First Instance in Case T-422/03 R *Enviro Tech Europe and Enviro Tech International* v *Commission* [2004] ECR II-469, dismissed that application for interim measures.

26 By a document dated 5 April 2004 and registered at the Court Registry on the same day, the applicants lodged a further application for interim measures under Articles 242 EC and 243 EC, seeking inter alia that the President of the Court order the suspension of 'the inclusion by the Commission of nPB in the 29th adaptation to technical progress of Directive 67/548'. In their application, the applicants stated that the meeting of the Regulatory Committee to adopt the proposed 29th adaptation to technical progress of Directive 67/548 was scheduled for 14 April 2004.

27 On 29 April 2004, the Commission formally adopted Directive 2004/73, which classifies nPB as a highly flammable substance (R 11) and as a category 2 reproductive toxicant (R 60).

28 An order made on 2 July 2004 by the President of the Court of First Instance in Case T-422/03 R II *Enviro Tech Europe and Enviro Tech International* v *Commission* [2004] ECR II-2003, dismissed the second application for interim measures.

29 By application registered at the Court Registry on 20 July 2004, the applicants brought an action seeking the partial annulment of Directive 2004/73 and an action for damages.

30 By separate act lodged at the Court Registry on 7 September 2004, the defendant put forward a plea of inadmissibility pursuant to Article 114 of the Rules of Procedure of the Court of First Instance. The applicants submitted their observations on that plea on 25 October 2004.

31 By separate act, registered at the Court Registry on 3 November 2004, the applicants brought this application for interim measures. In this application they asked the President of the Court of First Instance to adjudicate on the application, under Article 105(2) of the Rules of Procedure, before the Commission submitted its observations.

32 On 15 November 2004, the Commission submitted its observations on the application for interim measures.

Forms of order sought

33 In their present application, the applicants claim that the President of the Court should:

— 'declare the present application admissible and well founded';

— 'declare that interim relief is necessary to prevent irreparable harm to the applicants';

— 'suspend the inclusion of nPB in Commission Directive [2004/73] pending the full resolution of the dispute in the main proceedings';

— 'order the Commission to notify the suspension measure to the Member States so as to prevent the implementation of the nPB reclassification by the Member States pending the full resolution [of the dispute] in the main proceedings';

— 'order the Commission to pay all costs of these proceedings'.

34 The Commission contends that the President of the Court should:

— dismiss the application for interim measures;

— order the applicants to pay the costs.

Law

35 Article 104(2) of the Rules of Procedure provides that an application for interim measures must state the subject-matter of the proceedings, the circumstances giving rise to urgency and the pleas of fact and law establishing a prima facie case (*fumus boni juris*) for the interim measures applied for. Those conditions are cumulative and therefore an application for interim measures must be dismissed if any one of them is absent (order of the President of the Court of Justice of 14 October 1996 in Case C-268/96 P(R) *SCK and FNK* v *Commission* [1996] ECR I-4971, paragraph 30). The judge hearing an application for interim measures must also, where appropriate, weigh up the interests involved (order of the President of the Court of Justice of 23 February 2001 in Case C-445/00 R *Austria* v *Council* [2001] ECR I-1461, paragraph 73).

36 Furthermore, in the context of that overall examination, the judge hearing the application enjoys a broad discretion and is free to determine, having regard to the specific circumstances of the case, the manner and order in which those various conditions are to be examined, there being no rule of Community law imposing a pre-established scheme of analysis within which the need to order interim measures must be assessed (order of the President of the Court of Justice of 19 July 1995 in Case C-149/95 P(R) *Commission* v *Atlantic Container Line and Others* [1995] ECR I-2165, paragraph 23).

37 It is in the light of the principles restated above that this application for interim measures must be examined.

Arguments of the parties

Admissibility

38 In its observations, the Commission submits that the main action and, as a consequence, the application for interim measures are manifestly inadmissible. To that end, the Commission maintains that Directive 2004/73 is a measure of general application and that it is not of individual concern to the applicants.

39 Likewise, as regards the applicants' action for damages, the Commission contends that, when an application for interim measures is connected with a claim for compensation for damage suffered as a consequence of an act which cannot be challenged in an action for annulment, it is only in very specific circumstances that an applicant may have a legitimate interest in the granting of interim measures (order of the President of the Court of First Instance of 12 December 1995 in Case T-203/95 R *Connolly* v *Commission* [1995] ECR II-2919). The applicants have given no indication that such circumstances exist in this case.

40 The applicants, on the other hand, maintain that they have standing to challenge Directive 2004/73 under the fourth paragraph of Article 230 EC on the three grounds set out below.

41 First, Community case-law has established that an action for annulment may be brought against all measures adopted by the institutions which are intended to have legal effects, whatever their nature or form.

42 Second, the applicants are individually concerned by Directive 2004/73 because they have participated in the administrative assessment of nPB, which is distinct from the legislative process leading to the adoption of Directive 2004/73. The applicants' involvement in the administrative assessment of nPB derives as a minimum from the Commission's established practice and thus is customary, which places the applicants in a special position. Furthermore, during the administrative review of nPB, the Commission failed to comply with its duty to assess the applicants' data and complaints carefully and impartially, which failure is subject to judicial review (Case T-54/99 *max.mobil* v *Commission* [2002] ECR II-313).

43 Third, the applicants claim that they enjoy a specific pre-existing patent right to use Ensolv, which distinguishes them individually (see, to that effect, Case C-309/89 *Codorniu* v *Council* [1994] ECR I-1853). The applicants also submit that the 'right to (intellectual) property' and the right to exercise a commercial activity are fundamental rights.

44 Finally, the applicants add that they have brought an action for damages for which they fully meet the requirements on standing.

Prima facie case

45 The applicants submit that their main action is prima facie founded. In adopting Directive 2004/73, the Commission (i) merely endorsed the Working Group

recommendation, (ii) failed to comply with its duty to base its decisions on the latest scientific developments, (iii) failed to review the documents submitted by the applicants carefully and impartially and (iv) denied the applicants the right to be heard.

46 As a result, Directive 2004/73 is manifestly unlawful since, first, it is founded on a manifest error of assessment and infringes Articles 3, 4 and 5 of, and Annex V, point A.9, Annex VI, point 4.2.3, and Annex VI, point 1.1, to Directive 67/548. Second, Directive 2004/73 violates the applicants' legitimate expectation that their data would be assessed diligently, impartially and in accordance with the relevant provisions of Directive 67/548. Third, Directive 2004/73 is in breach of Article 95 (3) EC. Fourth, it infringes the precautionary principle. Fifth, the applicants submit that the Commission was not competent to adopt Directive 2004/73 and that the directive infringes the principles of legal certainty, legitimate expectations, independence and excellence of scientific advice, proportionality and equal treatment, the prohibition on the misuse of powers, the duty of surveillance and the principle of sound administration. By adopting Directive 2004/73, the Commission also infringed the applicants' right to be heard and its own duty to carry out a diligent and impartial review.

Urgency

47 In their application, the applicants submit that it is a mater of urgency to prevent the implementation of Directive 2004/73 and to forestall its irreparable commercial and regulatory consequences.

48 First, the classification of nPB as a highly flammable substance will require the applicants to comply with a set of rules and safety requirements which will prevent them from continuing to supply their product to their customers. Mixtures such as

Ensolv must be classified on the basis of their components pursuant to the provisions of Directive 67/548 in conjunction with those of Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ 1999 L 200, p. 1). As is prescribed by point 2.2.5 of Annex VI to Directive 67/548, preparations containing a flammable substance must be classified as such, unless the preparation 'could not in any way support combustion'. That exception does not concern highly flammable substances and thus can no longer be used following the reclassification of nPB. Adverse consequences therefore follow for the applicants' ability to continue marketing their one and only product, which endangers their continued existence.

49 In particular, the applicants will have to alter their promotional material. In addition, they will have to modify their 'safety data sheets' prepared pursuant to Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Council Directive 88/379/EEC (OJ 1991 L 76, p. 35). They will also have to modify their production and transportation process and inform their customers that they will be required to make significant changes to their storage, handling and transportation practices. Faced with these new burdens and the related costs, arising inter alia from sharp increases in insurance premiums, Ensolv will no longer be regarded as an attractive substitute for more dangerous substances, which will negate its commercial advantage. Since the applicants' business is based solely on that product, their survival is jeopardised.

50 Further, the category 2 reproductive toxicity classification ensures that nPB, and in turn Ensolv, will have to be withdrawn from the market within the shortest possible timeframe under 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 (OJ 1999 L 85, p. 1). The new classification will also entail a change in the authorisation procedure for nPB under the forthcoming 'REACH Regulation'.

51 Finally, the effect of reclassifying nPB will be that the applicants' patented mixture 'no longer fulfils, or is denied, its commercial function, and therefore is deprived of purpose'. The applicants' patent relating to Ensolv and to the underlying cleaning technology of vapour degreasing relies on the non-flammable and non-hazardous nature of nPB as described in the patent. The reclassification removes the patent's technical value, 'thereby nullifying ... [the] applicants' market position linked to such patent'. If nPB were phased out or were no longer purchased because of certain regulatory and financial constraints, they will cease to operate and consequently future losses and damage would be neither quantifiable nor reparable.

52 Responding to those arguments, the Commission contends that the applicants have overstated the harm which they will suffer and that any harm can be compensated by an award of damages.

53 In the first place, the applicants are not sufficiently specific about the effect of Directive 2004/73 on their patent. First, the patent states nothing about the flammable qualities of nPB itself. Second, whilst nPB was classified as flammable in 1991, the patent was applied for on 23 December 1996 and was granted on 29 September 1999. Nor does the Commission understand how reclassification of nPB as a category 2 reproductive toxicant has an effect on the patent concerned. Moreover, the applicants have not demonstrated either that the reclassification of nPB would affect the cleaning method covered by the patent or that it would be impossible to replace nPB by another solvent.

54 In the second place, the Commission doubts that the applicants' analysis of the effect of Directive 67/548 in conjunction with Directive 1999/45 is correct, as regards, in particular, the need to reclassify Ensolv, as opposed to nPB alone, as a highly flammable preparation.

55 In the third place, the Commission submits that the reclassification of nPB as a category 2 reproductive toxicant, first of all, does not inevitably lead to the withdrawal of nPB under Directive 1999/13.

56 Further, the applicants' arguments about the possible effects of the 'REACH Regulation' are speculative and conjectural, since, for one thing, the regulation has not yet been adopted and, for another thing, it is impossible to anticipate in advance the results of the tests which will have to be carried out in that regard.

57 The Commission also notes that the fact that the applicants have lodged a claim for damages but have not, however, requested payment of a sum on account or an interim award shows that they themselves consider that a financial award could constitute adequate compensation.

58 Furthermore, even on the assumption that the applicants lose market shares, they have not shown that recovering a significant proportion of their market shares, in particular by putting into place appropriate publicity measures, would be impossible because of obstacles of a structural or legal nature (order of the President of the Court of Justice of 11 April 2001 in Case C-471/00 P(R) *Commission* v *Cambridge Healthcare Supplies* [2001] ECR I-2865, paragraphs 110 and 111).

59 Lastly, the applicants have failed to demonstrate how Directive 2004/73 could cause them to discontinue their business. The Commission adds that the absence of proof in respect of that harm is particularly significant since, first, it is unlikely that Directive 2004/73 will produce effects before the deadline set for its implementation, namely 31 October 2005, and, second, to date, no Member State has notified the Commission that it has implemented the directive.

Findings of the President

60 Since the parties' written observations contain all the information necessary to adjudicate on the application for interim measures, there is no need to hear oral argument from the parties.

61 By virtue of settled case-law, the admissibility of the main action, in principle, should not be examined in relation to an application for interim measures so as not to prejudge the substance of the case. Where — as in the present case — it is contended that the main action to which the application for interim measures relates is manifestly inadmissible, it may none the less prove necessary to establish whether there are any grounds for concluding, prima facie, that the main action is admissible (orders of the President of the Court of First Instance of 15 February 2000 in Case T-1/00 R *Hölzl and Others* v *Commission* [2000] ECR II-251, paragraph 21, and of 8 August 2002 in Case T-155/02 R *VVG International and Others* v *Commission* [2002] ECR II-3239, paragraph 18).

62 Under the fourth paragraph of Article 230 EC, 'any natural or legal person may ... institute proceedings against a decision addressed to that person or against a decision which, although in the form of a regulation or a decision addressed to

another person, is of direct and individual concern to the former'. Although Article 230 EC, fourth paragraph, makes no express provision regarding the admissibility of actions brought by individuals for annulment of a directive, it is nevertheless clear from the case-law that that fact in itself is not sufficient to render such an action inadmissible (Case T-135/96 *UEAPME* v *Council* [1998] ECR II-2335, paragraph 63, and order of the Court of First Instance of 10 September 2002 in Case T-223/01 *Japan Tobacco and JT International* v *Parliament and Council* [2002] ECR II-3259, paragraph 28).

63 In accordance with settled case-law, a measure is of general application if it applies to objectively determined situations and produces its legal effects with respect to categories of persons envisaged generally and in the abstract (Case T-482/93 *Weber* v *Commission* [1996] ECR II-609, paragraph 55, and order of the Court of First Instance of 15 December 2000 in Case T-113/99 *Galileo and Galileo International* v *Council* [2000] ECR II-4141, paragraph 48).

64 In this instance, the amendment of the rules on the classification and labelling of nPB, as deriving from Directive 2004/73, produces certain effects for manufacturers and users of nPB in the Community. Consequently, prima facie, Directive 2004/73 applies to objectively determined situations and produces legal effects with respect to categories of persons envisaged generally and in the abstract. Prima facie, the directive is therefore, by virtue of its nature and its scope, general.

65 However, it is not impossible that a provision which, by its nature and scope, is of general application may be of individual concern to natural or legal persons when it affects them by reason of certain attributes peculiar to them, or by reason of a factual situation which differentiates them from all other persons and distinguishes them individually in the same way that the addressee of a decision would be so distinguished (Case C-358/89 *Extramet Industrie* v *Council* [1991] ECR I-2501, paragraph 13; *Codorniu* v *Council*, cited at paragraph 43 above, paragraph 19; and Case C-451/98 *Antillean Rice Mills* v *Council* [2001] ECR I-8949, paragraph 49).

66 In this case, in light of the arguments put forward by the applicants, there are serious doubts as to whether they are individually concerned by Directive 2004/73.

67 In the first place, the fact that a person participates in one way or another in a process leading to the adoption of a Community act does not distinguish that person individually in relation to the act in question unless the relevant Community legislation has laid down specific procedural guarantees for such a person (orders of the Court of First Instance of 3 June 1997 in Case T-60/96 *Merck and Others* v *Commission* [1997] ECR II-849, paragraph 73, and of 15 September 1998 in Case T-109/97 *Molkerei Großbraunshain and Bene Nahrungsmittel* v *Commission* [1998] ECR II-3533, paragraphs 67 and 68).

68 In this instance it does not appear, prima facie, that the provisions relied on by the applicants in their application for interim measures confer relevant procedural rights in respect of the process adapting Directive 67/548 to technical progress. In particular, point 1.2 of Annex VI to Directive 67/548, which provides that the annex 'is addressed to all those concerned (manufacturers, importers, national authorities) with methods of classifying and labelling dangerous substances and preparations', cannot be regarded as conferring such a procedural guarantee on the applicants. The same is true, prima facie, of points 1.7.2 and 4.1 of Annex VI to Directive 67/548. At first sight, those provisions only confer on manufacturers, importers and distributors the power or the duty to submit certain information or proposals to the Member States but do not confer on them any particular procedural right for the purposes of the process of adapting Directive 67/548 to technical progress.

69 Furthermore, the applicants seem to draw support for their arguments from the fact that they took part in an 'administrative process' distinct from the 'legislative process' leading to the adoption of Directive 2004/73. It must none the less be stated

that, prima facie, that distinction merely underlines the fact that the applicants are not distinguished individually in relation to the measure finally adopted, at least in the absence of any specific procedural guarantee afforded to them for the purpose of the adoption of that measure. On that last point, the evidence put forward by the applicants in their application for interim measures does not show, prima facie, that they are individually concerned by Directive 2004/73 by reason of a right established by the Commission's practice or by 'custom', which would allow them to take part in the 'administrative process' preceding the adoption of Directive 2004/73. Similarly, it is prima facie to no avail that the applicants refer to the Commission's obligation to examine their letters of 29 August and 29 September 2003 diligently and impartially. In fact, prima facie, such an obligation did not require the Commission to have regard to the applicants' particular situation for the purposes of the adoption of Directive 2004/73 or to involve them in any specific way in the process for adopting that act.

70 Second, contrary to the applicants' submission, it does not appear, prima facie, that on account of the licence to use the patent relating to Ensolv, they are in a comparable situation to that of the applicant in *Codorniu* v *Council* (paragraph 43 above). In that case, the provision at issue, by reserving the right to use the term 'crémant' to French and Luxembourg producers alone, had prevented Codorniu from using a graphic trade mark which it had been using since 1924. At first sight, the evidence advanced by the applicants does not permit of a finding that Directive 2004/73 prevents them from using their exclusive rights or, in the alternative, deprives them of such rights.

71 There are therefore serious grounds for doubting that the applicants are individually concerned by Directive 2004/73. Nevertheless, the President concludes that it is not necessary in the circumstances of this case to proceed further with his examination of the prima facie admissibility of the application for annulment. Nor is it necessary to reach a decision on the arguments raised by the Commission concerning the inadmissibility of the application which are based on the fact that the application is connected with a claim for compensation for damage suffered as a consequence of an act which cannot be challenged in an action for annulment. In any event the applicants have not established urgency in relation to the interim measures sought.

72 On that point, it is appropriate to bear in mind that the urgency of an application for interim measures must be assessed in relation to the necessity for an interim order in order to prevent serious and irreparable damage to the party applying for those measures (orders of the President of the Court of Justice of 6 February 1986 in Case 310/85 R *Deufil* v *Commission* [1986] ECR 537, paragraph 15, and of the President of the Court of First Instance of 30 June 1999 in Case T-13/99 R *Pfizer Animal Health* v *Council* [1999] ECR II-1961, paragraph 134). It is for that party to prove that it cannot wait for the outcome of the main proceedings without suffering damage of that kind (orders of the President of the Court of Justice of 8 May 1991 in Case C-356/90 R *Belgium* v *Commission* [1991] ECR I-2423, paragraph 23, and of the President of the Court of First Instance of 15 November 2001 in Case T-151/01 R *Duales System Deutschland* v *Commission* [2001] ECR II-3295, paragraph 187).

73 It is not necessary for the imminence of the damage to be demonstrated with absolute certainty, it being sufficient to show that damage — especially if its occurrence depends on a series of factors — is foreseeable with a sufficient degree of probability (order of the President of the Court of Justice of 14 December 1999 in Case C-335/99 P(R) *HFB and Others* v *Commission* [1999] ECR I-8705, paragraph 67). The applicant is none the less required to prove the facts forming the basis of its claim that serious and irreparable damage is likely (order in *HFB and Others* v *Commission*, cited above, paragraph 67).

74 Finally, although it is firmly established that damage of a purely pecuniary nature cannot, otherwise than in exceptional circumstances, be regarded as irreparable or even as reparable with difficulty, since it may be the subject of subsequent pecuniary compensation (order of the President of the Court of 18 October 1991 in Case C-213/91 R *Abertal and Others* v *Commission* [1991] ECR I-5109, paragraph 24, and order of the President of the Court of First Instance of 28 May 2001 in Case T-53/01 R *Poste Italiane* v *Commission* [2001] ECR II-1479, paragraph 119), it is also established that an interim measure is justified if it appears that, if the measure were not granted, the applicant would find itself in a situation which could jeopardise its

very existence or irremediably alter its position in the market (see, to that effect, orders of the President of the Court of First Instance of 20 July 2000 in Case T-169/00 R *Esedra* v *Commission* [2000] ECR II-2951, paragraph 45, and Case T-148/04 R *TQ3 Travel Solutions Belgium* v *Commission* [2004] ECR II-3027, paragraph 46).

75 In this instance it is necessary to consider whether the applicants have sufficiently established that the reclassification of nPB, as resulting from Directive 2004/73, is liable to harm their interests to the point of causing them serious and irreparable damage before the Court reaches a decision in the main action.

76 In that regard, a separate analysis must be carried out of each of (i) the effects of the classification of nPB as a highly flammable substance on the applicants' commercial and financial situation, (ii) the effects of the classification of nPB as a category 2 reproductive toxicant on their commercial and financial situation and (iii) the effects of both those classifications on the applicants' rights over the patent relating to Ensolv.

77 As regards, in the first place, the classification of nPB as a highly flammable substance, the applicants state, in essence, that, on account of the provisions of Directive 67/548, as amended, in conjunction with Directive 1999/45, Ensolv must be classified as a highly flammable preparation. That classification would require the applicants to change their promotional material, their 'safety data sheets' and their production and transport practices. Furthermore, given the drawbacks linked to the classification of Ensolv, it would no longer be differentiated from other products and its use would involve prohibitive costs: that would negate the marketing advantage which it has gained over recent years.

78 On the assumption, however, that the classification of nPB as a highly flammable substance actually does entail reclassification of Ensolv (which the Commission doubts), the fact would remain that in any event the applicants do not produce any evidence showing that such a change is likely to have serious and irreparable consequences for their financial and commercial situation.

79 First of all, the applicants do not adduce any evidence allowing an assessment to be made of the financial costs which they will allegedly bear as a result of changes to their marketing material, their 'safety data sheets' and their production and transport practices.

80 Second, the arguments and evidence advanced by the applicants in their application for interim measures are both too imprecise and insufficient to determine whether any constraints which might be imposed on their customers because of the possible classification of Ensolv as a highly flammable product will in fact occur and how serious they would be. The evidence is also insufficient to evaluate the characteristics of the market in which Ensolv is present, such as the characteristics of competing products, and, a fortiori, to establish that the reclassification of nPB and, as the case may be, of Ensolv will entail a serious and irreparable reduction in either the applicants' turnover or their market shares.

81 In that regard, the affidavit of one of the directors of Enviro Tech Europe, which is annexed to the application for interim measures, cannot be regarded as sufficiently probative to establish the alleged effects.

82 Nor can the affidavit of one of the applicants' distributors (also attached to the application for interim measures) be regarded as sufficiently probative. In that

affidavit, the distributor concerned states that, in so far as his customers cease to buy Ensolv, he himself will cease to place orders with the applicants. However, the distributor's statements are not sufficient to establish either that that is how his end customers would react or, if they were to react in that way, how serious the consequences would be for the applicants. Nor do the applicants specify what proportion of their total sales is represented by the purchases of that distributor, who appears moreover to be active only in the United Kingdom and Ireland.

83 Furthermore, even on the assumption that the applicants had sufficiently established that they would suffer a serious loss of market shares because of the reclassification of nPB, they would none the less have failed to establish that obstacles of a structural or legal nature existed which would prevent them from recovering a significant proportion of those market shares following the putting into place of, inter alia, appropriate publicity measures (see, by analogy, the order in *Commission* v *Cambridge Healthcare Supplies*, paragraph 58 above, paragraph 111).

84 Last, even supposing that the applicants had established that, as a result of the maintenance in force of Directive 2004/73, they would make no further sales of Ensolv in the Community, they would none the less not have established that their existence would be jeopardised because of that.

85 First, even though the applicants state that they market only one product, namely Ensolv, they give no indication of the proportion of their total turnover represented by their Community sales of Ensolv. It is thus not established that the applicants do not make sales outside the Community which would allow them to survive until the Court gives judgment in the main action.

86 Second, the applicants adduce no evidence relating to their current financial situation. In the absence of any such evidence, there is nothing to suggest that, even if they were to have to discontinue their business in the Community entirely, they would not have financial reserves allowing them to survive until the Court gives judgment in the main action.

87 In the light of the material in the case file, the classification of nPB as a highly flammable substance cannot be regarded as having serious and irreparable consequences for the applicants' financial and commercial situation.

88 As regards, in the second place, the consequences of classifying nPB as a category 2 reproductive toxicant, the applicants state in essence that it will result in the withdrawal of nPB and Ensolv from the market. Without it being necessary to decide whether such a consequence will actually ensue, it must be stated at the outset that, for the reasons mentioned above (paragraphs 84 to 86), the applicants have not established that they would suffer serious and irreparable harm even if they should have to discontinue all sales of Ensolv in the Community.

89 Further, in so far as the applicants maintain that the classification of nPB as a category 2 reproductive toxicant could cause them to lose market shares, they have not sufficiently established that there will actually be a loss, or the seriousness of the loss, or that there are obstacles of a structural or legal nature preventing them from recovering a significant proportion of any market shares which they might lose (see paragraph 83 above).

90 Finally, as regards the effects of the new authorisation procedure which will apply under the 'REACH programme', it must be stated that the regulations cited by the applicants have not yet been adopted and that any harm which might result is consequently purely hypothetical. Harm of that nature cannot provide grounds for granting the interim measures requested (see, to that effect, the orders of the President of the Court of First Instance of 15 July 1998 in Case T-73/98 R *Prayon-Rupel* v *Commission* [1998] ECR II-2769, paragraphs 22, 26 and 38; of 8 December 2000 in Case T-237/99 R *BP Nederland and Others* v *Commission* [2000] ECR II-3849, paragraphs 57 and 66; and of 15 January 2001 in Case T-241/00 R *Le Canne* v *Commission* [2001] ECR II-37, paragraph 37).

91 In the light of the material in the case-file, the reclassification of nPB as a category 2 reproductive toxicant cannot therefore be regarded as having serious and irreparable consequences for the applicants' financial and commercial situation.

92 Lastly, in the third place, it must be stated that the applicants' arguments that the patent for Ensolv is 'deprived of purpose' by the reclassification of nPB are too vague to prove the prospect of serious and irreparable harm. In so far as the applicants are seeking to show that the reclassification of nPB could affect, from a legal point of view, their exclusive rights, their arguments are not sufficiently precise, detailed or substantiated to establish that such effects are probable, serious and irreparable. Furthermore, in so far as, by their arguments, the applicants are seeking to show that the maintenance in force of Directive 2004/73 will have an adverse effect on the commercial value of their licence, in the absence of any evidence relating to their financial situation, they have also failed to establish (i) that such harm would be serious (see, to that effect, the order of the President of the Court of Justice of 23 May 1990 in Joined Cases C-51/90 R and C-59/90 R *Comos-Tank and Others* v *Commission* [1990] ECR I-2167, paragraph 26), (ii) that the applicants' existence could be imperilled (see paragraphs 85 and 86 above) and (iii) that the harm cannot be compensated by a financial award.

93 The applicants have thus not established that they were at risk of suffering serious and irreparable harm as a result of the maintenance in force of Directive 2004/73. As a consequence, without there being any need to consider the condition relating to a prima facie case and to weigh up the interests involved, the application for interim measures must be dismissed.

On those grounds,

THE PRESIDENT OF THE COURT OF FIRST INSTANCE

hereby orders:

1. The application for interim measures is dismissed.

2. Costs are reserved.

Luxembourg, 10 February 2005.

H. Jung — B. Vesterdorf

Registrar — President