ORDER OF THE PRESIDENT OF THE COURT OF FIRST INSTANCE

2 July 2004 *

In Case T-422/03 R II,

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

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

applicants,

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

v

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

defendant,

* Language of the case: English.

APPLICATION seeking, first, 'suspension of the nPB entry' in the 29th adaptation to technical progress of 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); secondly, suspension of the entry for nPB in Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Directive 67/548 (OJ 2004 L 152, p. 1); and, thirdly, that other interim measures be ordered,

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 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 in 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 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.

6 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

7 Pursuant to Article 28 of Directive 67/548, as amended:

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

8 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 CMR 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 CMR Working Group, the Commission submits the draft measures to the committee established by Article 29 of Directive 67/548 ('the Regulatory Committee').

9 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.'

10 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

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

12 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.

13 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.

14 At the meeting of the CMR 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.

15 Subsequently, in April 2002, the HSE proposed the classification of nPB as a highly flammable substance, based on a new test result.

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

17 At its January 2003 meeting, the CMR 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 CMR Working Group to re-open its discussions on nPB.

18 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 CMR Working Group's recommendations on nPB.

19 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 CMR Working Group ('the contested acts').

20 By application lodged at the Registry of the Court of First Instance on 23 December 2003, the applicants brought an action seeking the annulment of the contested acts and an action for damages.

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

22 By separate application lodged at the Court Registry on 30 December 2003, the applicants, in accordance with Articles 242 EC and 243 EC, brought a first application for interim measures, by which they requested the President of the Court of First Instance to suspend the operation of the contested acts 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, and thereafter, until such time as the Court of First Instance has given judgment in the main action.

23 In its observations, the Commission specified that the Regulatory Committee meeting was never fixed to take place on 15 January 2004 and that it had been postponed sine die.

24 An order made on 3 February 2004 dismissed the first application for interim measures (Case T-422/03 R *Enviro Tech and Another* v *Commission*, ECR II-469) ('the Order of 3 February 2004'). In that order, the President of the Court of First Instance essentially held that there was no need to rule on the admissibility of the main action, since suspension of the operation of the contested acts could not be of any use to the applicants as it could not prevent the Commission from proposing the reclassification of nPB. The President of the Court took the view that it was not necessary to examine the serious and irreparable harm invoked by the applicants, as the premisses on which it was based were in any event too hypothetical to justify granting interim measures.

25 By a separate document lodged at the Court Registry on 9 February 2004, the defendant put forward in the main action a plea of inadmissibility pursuant to Article 114 of the Rules of Procedure of the Court of First Instance.

26 By a document dated 5 April 2004 and lodged at the Registry of the Court of First Instance on the same day, the applicants filed a second 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. They also asked the President of the Court, pursuant to Article 105(2) of the Rules of Procedure, to grant the application before the Commission had submitted its observations.

27 On 7 April 2004, at the request of the President of the Court, the Commission confirmed that the meeting of the Regulatory Committee to adopt the draft text of the 29th adaptation to technical progress of Directive 67/548 was to take place on 14 April 2004.

28 On 13 April 2004, the applicants on their own initiative lodged at the Registry of the Court of First Instance certain documents which they said had come to their knowledge only after their application for interim measures had been lodged. The President of the Court decided to add those documents to the file.

29 On 23 April 2004, the Commission submitted its observations concerning those documents. The Commission also informed the President of the Court that on 14 April 2004 the Regulatory Committee had approved the proposed reclassification of nPB as, first, a highly flammable substance (R 11) and, secondly, as a reproductive toxicant under categories 2 (R 60) and 3 (R 63).

30 On 14 May 2004, the applicants submitted new documents to the President of the Court and informed him that, on 29 April 2004, the Commission had formally adopted Directive 2004/73 adapting to technical progress for the 29th time Council Directive 67/548 (OJ 2004 L 152, p. 1) and classifying nPB under categories R 11 and R 60. On the basis of that information, the applicants sought new forms of order, seeking suspension of the entry for nPB in Directive 2004/73. On 17 May 2004, the President of the Court decided to add those new documents to the file. On 26 May 2004, the Commission submitted its observations on those new documents and forms of order sought.

Forms of order sought

31 In the present application, the applicants ask the President of the Court:

— 'to declare the present application admissible and well founded' ('the first request');

— 'to declare that interim relief is necessary to prevent irreparable harm to the applicants' ('the second request');

— 'to suspend the inclusion by the Commission of nPB in the 29th adaptation to technical progress of Directive 67/548 pending the full resolution of the dispute in the main proceedings' ('the third request');

— 'to adopt any other interim relief measures the President of the Court deems appropriate to prevent the reclassification of nPB as R 11 and R 60' ('the fourth request');

— to order the Commission to pay the costs.

32 In their letter of 14 May 2004, the applicants also request the President of the Court to:

— 'suspend the nPB entry in the 29th adaptation to technical progress' of Directive 67/548 ('the fifth request');

— 'order the Commission to give immediate notice to the Member States that such entry is suspended pending the full outcome of the dispute in the main action' ('the sixth request');

— 'issue such other order as necessary to effectively achieve interim relief for the applicants' ('the seventh request').

33 The Commission claims that the President of the Court should:

— dismiss the application for interim measures;

— order the applicants to pay the costs.

Law

34 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, so that 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). Where appropriate, the judge hearing such an application must also 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).

35 Furthermore, in the context of that overall examination, the judge hearing the application enjoys 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 analysed and 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).

Arguments of the parties

Admissibility

36 In its observations, the Commission, while pointing out that the applicants seek the suspension of a measure different from that which they sought to have annulled in the main action, states that it is not necessary to examine that question, inasmuch as the main action for annulment and, in consequence, the application for interim measures, are manifestly inadmissible. In particular, as regards the admissibility of the main action, the Commission maintains that the action for annulment is manifestly inadmissible because the applicants purport to impugn acts which do not affect their legal position.

37 The applicants, for their part, maintain that they are entitled to bring proceedings against the contested acts pursuant to the fourth paragraph of Article 230 EC, inasmuch as those acts are Commission decisions signed by a director and directly addressed to them. The applicants are therefore not required to demonstrate that the contested acts are of direct and individual concern to them, since that criterion applies only to decisions addressed to third parties. The applicants also state that they are entitled to act on the sole basis of the reasoning followed by the Court of First Instance in Case T-54/99 *max.mobil* v *Commission* [2002] ECR II-313, paragraph 71.

Prima facie case

38 The applicants are of the opinion that their action against the contested acts is not manifestly unfounded. The main points of the applicants' arguments concerning *fumus boni juris* are set out in greater detail in paragraphs 36 to 40 of the order of 3 February 2004.

Urgency

39 In their application of 5 April 2004, the applicants submit that interim measures are necessary because there is an urgent need to prevent the adoption, at that time scheduled for 14 April 2004, of the 29th adaptation to technical progress of Directive 67/548. In particular, the applicants claim that the adoption and implementation of the Commission decision to reclassify nPB, which ensures its reclassification under the 29th adaptation to technical progress of Directive 67/548, produces three adverse consequences resulting in damage for the applicants which is severe, irreversible and can be established with a sufficient degree of certainty.

40 First, the applicants submit that the new classification of nPB as highly flammable and as a category 2 reproductive toxicant nullifies their patent on Ensolv, inasmuch as it is based on the non-flammable and non-hazardous properties of nPB.

41 Next, according to the applicants, the new classification of nPB as highly flammable requires them, first, to identify that product as such and to modify their safety data sheet; secondly, to alter their transport, handling and storage practices; and thirdly, to advise their clients to do the same, as a result of the provisions of Directive 67/548

in conjunction with 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). In the light of those constraints, the applicants' clients would no longer differentiate between Ensolv and other products. Inasmuch as the applicants' activities rest solely on that product, their survival would therefore be at risk.

42 Finally, the applicants stress that the new classification of nPB as a reproductive toxicant of category 2 requires them immediately to propose and within the shortest possible time implement the replacement of nPB with 'safer' alternatives 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). That new classification would also entail changing the authorisation system for nPB under the future 'REACH' regulation.

43 The applicants add that if nPB is phased out or is no longer purchased by customers owing to regulatory and financial constraints, the applicants will cease to operate, so that the amount of future loss and damage is neither quantifiable nor reparable.

Balance of interests

44 As regards the balance of interests, the applicants point out in their application that the orders requested would do no more than maintain the current situation until the final resolution of the matter in the main proceedings.

45 Rejecting the premiss that nPB can be classified as flammable without this being supported by adequate test results, the applicants consider that the current classification is sufficient to warn users of nPB about its alleged flammable properties. Classification as a highly flammable substance would achieve no further purpose but would drive the applicants out of business before the full resolution of the matter in the main proceedings. The applicants further note that since the introduction of nPB in Europe and in the rest of the world there has never been any reported incident due to the alleged flammable properties of this substance.

46 According to the applicants, the same reasoning could be applied to the proposed reclassification of nPB as a reproductive toxicant of category 2, as in the absence of interim relief the applicants would have to present immediately and implement within the shortest possible time a phase-out plan for nPB under Directive 1999/13. In the alternative, the applicants would be prepared temporarily to classify their nPB product as a category 3 reproductive toxicant pending the final resolution of the matter in the main proceedings.

47 Finally, the applicants note that the granting of a suspension order is all the more important in the present case as there is also a need to clarify, first, that the Commission cannot classify substances without using the testing methods and classification criteria specifically provided for in Directive 67/548; second, that the precautionary principle cannot be applied in hazard-based classification decisions; and third, the role and powers of the CMR Working Group to adopt policy decisions.

Findings of the President

48 First of all, compliance with the Rules of Procedure and, in particular, the conditions as to the admissibility of applications for interim relief are a matter of public policy

(see, to that effect, the order of the President of the Court of First Instance of 7 May 2002 in Case T-306/01 R *Aden and Others* v *Council and Commission* [1996] ECR II-2387, paragraphs 43 to 46).

49 The President takes the view that since the file as it stands provides all the information needed to give judgment on the application for interim measures, there is no need to hear oral argument from the parties.

50 The President considers that in the present case the requests made by the applicants, set out in paragraphs 31 and 32 above, should be analysed in turn, and there is no need to rule on whether the main action is prima facie manifestly inadmissible.

51 First, without its being necessary to determine whether the first and second requests could in themselves be of use to the applicants, it is clear that the question as to whether the aforesaid requests should be granted depends on the admissibility and merits of the other requests.

52 Secondly, it must be noted from the outset that the wording of the third request, which seeks the suspension of 'the inclusion by the Commission of nPB in the 29th adaptation to technical progress of Directive 67/548', is particularly ambiguous. Since 'the inclusion ... of nPB in the 29th adaptation to technical progress of Directive 67/548' can only occur, literally, on the final adoption of that text, it appears that the third request must be interpreted as seeking the suspension of the implementation of the final text adopted by the Commission. Nevertheless, certain passages of the application for interim measures also seem to indicate that the applicants are in fact asking the President to prevent the Commission and/or the Regulatory Committee from exercising their legislative powers for the purpose of the

29th adaptation to technical progress of the Directive. That is the case in particular for the passages where the applicants state that they seek to prevent the adoption of the Commission's proposal to the Regulatory Committee.

53 It appears that the third request must in any event be rejected, without any need to rule on whether its lack of clarity is sufficient to render it inadmissible.

54 First, inasmuch as the third request must be interpreted as seeking to prevent the Commission and/or the Regulatory Committee from exercising their legislative powers for the purpose of including nPB in the 29th adaptation to technical progress of Directive 67/548, it must be considered together with the fourth request, which asks the President to 'adopt any other interim relief measures ... appropriate to prevent the reclassification of nPB as R 11 and R 60'.

55 It is not necessary to examine whether those two requests are admissible and, in particular, whether it is contrary to the principles of the division of powers among the various Community institutions to order interim measures which prevent the Commission and the Regulatory Committee, even provisionally, from exercising their powers as regards legislation (see, by analogy, the orders of the President of the Court of First Instance of 12 July 1996 in Case T-52/96 R *Sogecable* v *Commission* [1996] ECR II-797, paragraphs 39 to 41, and of 5 December 2001 in Case T-216/01 R *Reisebank* v *Commission* [2001] ECR II-3481, paragraph 52), since those requests are henceforth devoid of purpose inasmuch as the Commission adopted Directive 2004/73 on 29 April 2004.

56 Secondly, if the third request should be interpreted as seeking the suspension of the nPB entry in the 29th adaptation to technical progress of Directive 67/548 it must be

considered together with the fifth request, which seeks to have the entry for nPB in Directive 2004/73 suspended. It is clear, however, that those two requests seek suspension of the operation of an act which the applicants did not challenge in the main action, contrary to the first paragraph of Article 104(1) of the Rules of Procedure.

57 The third, fourth and fifth requests must therefore be rejected.

58 Consequently, the sixth request, which asks the President to order the Commission immediately to notify the Member States that that inclusion is suspended pending the full resolution of the dispute in the main proceedings, must also be rejected.

59 Finally, it must be observed that the applicants do not provide sufficient clarification of the seventh request in their application, which asks the President to 'issue such other order as necessary to effectively achieve interim relief for the applicants' and which is vague and imprecise. Without further details as to its subject-matter, such a request does not meet the criteria laid down in Article 44(1)(d) of the Rules of Procedure to which Article 104(3) of those rules refers and is thus inadmissible (see, to that effect, the order of the President of the Court of First Instance of 12 February 1996 in Case T-228/95 R *Lehrfreund* v *Council and Commission* [1996] ECR II-111, paragraph 58).

60 Accordingly, in the light of all the foregoing considerations, the requests put forward by the applicants must in any event be rejected. Consequently, the application for interim measures must be dismissed in its entirety.

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, 2 July 2004.

H. Jung — B. Vesterdorf

Registrar — President