ORDER OF THE PRESIDENT OF THE COURT OF FIRST INSTANCE
16 January 2004 *

In Case T-369/03 R,

Arizona Chemicals BV, established in Almere (Netherlands),

Eastman Belgium BVBA, established in Kallo (Belgium),

Resinall Europe BVBA, established in Brugge (Belgium),

Cray Valley Iberica SA, established in Madrid (Spain),

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

applicants,

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 for, first, suspension of an act of the Commission dated 20 August 2003 and of the current entry for rosin under Annex I to 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) and, second, an order requiring the Commission to propose the declassification of rosin at the next Regulatory Committee meeting scheduled for the adaption of Directive 67/548 to technical progress,

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

makes the following

Order

Relevant legislation

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 (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 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).

General framework

3 Article 4 of Directive 67/548, as amended, provides that substances shall be classified on the basis of their intrinsic properties according to the categories of danger laid down in Article 2(2).

4 Article 2(2)(k) of Directive 67/548, as amended, defines 'sensitising substances and preparations' as the substances and preparations 'which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitisation such that on further exposure to the substance or preparation, characteristic adverse effects are produced'.

5 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'). As regards R-phrases more particularly, Article 23(2) of Directive 67/548, as amended, provides that:

'Every package shall show clearly and indelibly the following:

...

(d) standard phrases (R-phrases) indicating the special risks arising from the dangers involved in using the substance. The wording of those R-phrases shall comply with that laid down in Annex III. The R-phrases to be used for each substance shall be as indicated in Annex I...'.

Adaptation of Directive 67/548 to technical progress

6 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.'

7 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'). This group is comprised of experts sent by the Member States, such as toxicologists and classification experts, representatives of the chemical industry and representatives of the particular segment 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').

8 Article 29 of Directive 67/548, as amended by Regulation No 807/2003, provides:

'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.'

9 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.

4. If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken and shall inform the European Parliament.

5. If the European Parliament considers that a proposal submitted by the Commission pursuant to a basic instrument adopted in accordance with the procedure laid down in Article 251 of the Treaty exceeds the implementing powers provided for in that basic instrument, it shall inform the Council of its position.

6. The Council may, where appropriate in view of any such position, act by qualified majority on the proposal, within a period to be laid down in each basic instrument but which shall in no case exceed three months from the date of referral to the Council.

If within that period the Council has indicated by qualified majority that it opposes the proposal, the Commission shall re-examine it. It may submit an amended proposal to the Council, re-submit its proposal or present a legislative proposal on the basis of the Treaty.

If on the expiry of that period the Council has neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures, the proposed implementing act shall be adopted by the Commission.'

Directive 1999/45/EC

10 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) lays down rules concerning the marketing of dangerous 'preparations', defined as 'mixtures or solutions composed of two or more substances'.

11 According to Article 1(2) of Directive 1999/45:

'This directive shall apply to preparations which:

— contain at least one dangerous substance within the meaning of Article 2,

and

— are considered dangerous within the meaning of Article 5, 6 or 7.'

12 According to Article 2(2)(k) of Directive 1999/45, 'sensitising substances and preparations' are defined as 'substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitisation such that on further exposure to the substance or preparation, characteristic adverse effects are produced'.

13 Pursuant to Article 10(1.1) of Directive 1999/45:

'Member States shall take all necessary measures to ensure that:

(a) preparations within the meaning of Article 1(2) cannot be placed on the market unless the labelling on their packaging satisfies all the requirements of this article and the specific provisions of Part A and B of Annex V.'

14 Point B(9) of Annex V to Directive 1999/45, which contains certain rules concerning preparations not classified as sensitising but containing at least one sensitising substance, reads as follows:

'The packaging of preparations containing at least one substance classified as sensitising and being present in a concentration equal to or greater than 0.1 % or in a concentration equal to or greater than that specified under a specific note for the substance in Annex I to Directive 67/548/EEC must bear the inscription: "Contains (name of sensitising substance). May produce an allergic reaction".'

Facts and procedure

15 Arizona Chemical BV, Eastman Belgium BVBA, Resinall Europe BVBA and Cray Valley Iberica, SA (the 'applicants') are companies engaged in the manufacture and sale of rosin and rosin derivatives.

16 Rosin is a naturally occurring substance derived from the pine tree and used for its adhesive and hydrophobic properties. Rosin may be included in a large variety of products such as paper, adhesives, paints and cosmetics.

17 Pursuant to Commission Directive 93/72/EEC adapting to technical progress for the 19th time Council Directive 67/548 (OJ 1993 L 258, p. 29), rosin was classified in Annex I to Directive 67/548 as a respiratory and skin sensitiser with the risk phrase R 42/43: 'may cause sensitisation by inhalation and skin contact.'

18 Pursuant to Commission Directive 94/69/EC of 19 December 1994 adapting to technical progress for the 21st time Council Directive 67/548 (OJ 1994 L 381, p. 1), rosin was declassified as R 42. Rosin remained, however, listed in Annex I as an inhalation sensitiser with the risk phrase associated with the products listed in the R 43 category, that is 'may cause sensitisation by skin contact.'

19 After that amendment was made, the applicants gathered and submitted to the European Chemicals Bureau and the CMR Working Group data and arguments in order to demonstrate that the R 43 classification for rosin is not scientifically correct and that only the oxidised form of rosin ('oxidised rosin'), which is a discrete substance, has the potential to cause sensitising effects.

20 At its meeting of October 1999 the CMR Working Group concluded that the declassification of rosin requested was 'scientifically justified'. It added, however, that declassification would 'decrease the level of protection within the present regulatory system and the available means of control' and decided to 'continue to search for solutions within the Substances and Preparations Directives, which would both have to be scientifically more accurate and maintain the level of protection'.

21 In September 2002, the CMR Working Group restated its conclusion that although declassification of rosin would be 'scientifically justified', it would 'decrease the level of protection within the present regulatory system and the available means of control'. Accordingly, it agreed that rosin 'should not be declassified for sensitising properties and not further discussed on the basis of current data'.

22 On 23 June 2003, the applicants sent a letter to the Commission by which they requested that it take such measures as were necessary to declassify rosin as a skin sensitiser.

23 On 20 August 2003, the Commission sent a letter to the applicants ('the contested act') in which it explained, *inter alia,* that fresh rosin reacts to sensitising compounds by contact with the oxygen of the ambient air when used and that rosin normally contains oxidised rosin which causes the sensitisation. The contested act also specifies that 'rosin is considered to be among the "top ten" allergens'. The contested act concludes that the applicants have not provided 'appropriate reasons to declassify rosin'.

24 By application lodged at the Registry of the Court of First Instance on 29 October 2003, the applicants brought an action seeking *inter alia:*

— the annulment of the contested act;

— a declaration that the entry for rosin in Annex I to Directive 67/548 is unlawful;

— in the alternative, a declaration that the entry for rosin in Annex I to Directive 67/548 is inapplicable to the applicants under Article 241 EC;

— compensation for the damage resulting from the adoption of the contested act.

25 Shortly thereafter, the applicants were informed that the Regulatory Committee would be meeting on 23 January 2004 to formally adopt the 29th adaptation to technical progress of Directive 67/548.

26 By separate application lodged at the Court Registry on 27 November 2003, the applicants, in accordance with Articles 242 EC and 243 EC, brought an application for interim measures, by which they request the President of the Court of First Instance:

— to declare their application admissible and well founded;

— to order the suspension of the contested act and of the current entry for rosin under Annex I to Directive 67/548 until such time as the Court of First Instance has given judgment in the main action;

— to order the Commission to propose the declassification of rosin under the 29th adaptation to technical progress of Directive 67/548 at the next Regulatory Committee meeting;

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

27 The applicants also requested, pursuant to Article 105(2) of the Rules of Procedure of the Court of First Instance, that the President grant the orders sought as a matter of extreme urgency before the Commission submitted its observations.

28 On 4 December 2003, the Commission filed its observations on the application for interim measures. In these observations, the Commission contends that the President should:

— reject the request for interim measures;

— order the applicants to pay the costs.

29 On 11 December 2003, the applicants and the Commission presented oral argument at a hearing.

30 On 7 January 2004, in response to a written question by the President, the Commission specified that the consultation of its different services on the measures contemplated for the purpose of the 29th adaptation of Directive 67/548 to technical progress had taken longer than expected and that the Regulatory Committee meeting, which was initially set down to take place on 23 January 2004, had been postponed *sine die*.

Law

31 Pursuant to article 104(2) of the Rules of Procedure an application for interim measures must state 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).

32 The measure requested must further be provisional inasmuch as it must not prejudge the points of law or fact in issue or neutralise in advance the effects of the decision subsequently to be given in the main action (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 22).

33 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 analysed and assessed (order in *Commission* v *Atlantic Container Line and Others*, cited at paragraph 32 above, paragraph 23).

34 It is in the light of the foregoing principles that the application for interim measures must be examined.

Arguments of the parties

Arguments presented by the applicants

— Admissibility

35 The applicants submit that they have standing to bring proceedings under Article 230(4) EC because the contested act is a Commission act, signed by a director, addressed directly to them, as a result of which they do not have to show that they are directly and individually concerned, such test relating only to measures addressed to a third party.

36 The applicants also submit that the contested act produces definitive legal effects that adversely affect their legal position in that it lays down the final position of the Commission on the classification of rosin. According to the applicants, the Commission decision not to propose the declassification of rosin as a skin sensitiser constitutes a final decision on rosin because the regulatory committee cannot vote ultra petitum and thus does not have the opportunity to reverse the Commission's determination.

37 The applicants further contend that even if the contested act was to be regarded as a preparatory act, it would still be subject to challenge under the reasoning followed by the Court of Justice in Case C-312/90 (*Spain* v *Commission* [1992] ECR I-4117) and Case C-47/91 (*Italy* v *Commission* [1992] ECR I-4145), in

which actions brought against preparatory measures, namely letters initiating the procedure provided for in Article 88(2) EC, were declared admissible.

— A prima facie case

38 The applicants maintain that their action against the contested act, which is based on six pleas in law, is not unfounded.

39 First, the applicants maintain that the analysis performed by the CMR Working Group within the European Chemicals Bureau — and endorsed by the Commission in the contested act — used data on the properties of oxidised rosin, and not those of rosin, even though the judgments made with respect to oxidised rosin properties cannot support a regulatory conclusion on the proper classification of rosin.

40 Second, the applicants contend that the current entry for rosin in Annex I to Directive 67/548 as well as the Commission decision not to declassify rosin are inaccurate and unlawful, as scientific evidence submitted to the CMR Working Group and the Commission demonstrates that rosin is not a skin sensitiser under the criteria of Directive 67/548.

41 Third, the applicants submit that the contested act is based on the false premiss that rosin always contains oxidised rosin when placed on the market and, by implication, that such oxidised rosin causes skin sensitisation, which is not the

case under normal conditions of handling and use. Therefore, the contested act is based on a fundamental error of fact, is scientifically inaccurate and violates the classification criteria under Annex VI to Directive 67/548.

42 Even assuming that rosin always contains oxidised rosin when placed on the market and that the Commission is entitled to classify rosin by reference to the properties of oxidised rosin, the contested act would still be inaccurate and unlawful because, first, the application of the test method relied upon by the Commission is inappropriate for oxidised rosin. Second, a more objective test shows that oxidised rosin would not present a risk to human health, and third, the form in which rosin is placed on the market does not contain oxidised rosin in toxicologically significant amounts that would cause sensitisation.

43 Fourth, the applicants consider that the CMR Working Group's refusal to recommend that rosin be declassified is contradictory in itself and is an implicit, but clear, invocation and application of the precautionary principle. The application of this principle to these circumstances is, however, factually, legally and technically improper.

44 Fifth, the applicants submit that the failure of the Commission to base its assessment on state-of-the-art data submitted by the applicants violates Article 95(3) EC. In addition, by requiring the applicants to demonstrate zero risk, the Commission ignores the requirement of Directive 67/548 to relate such analysis to normal conditions of handling and use.

45 Sixth, the failure of the Commission to take appropriate measures to declassify rosin as a skin sensitiser breaches a series of fundamental principles of Community law, such as proportionality, the need for legal certainty and protection of the applicants' legitimate expectations.

— Urgency

46 The applicants submit that the forms of order sought must be adopted urgently in order to prevent the adoption of the 29th adaptation to technical progress of Directive 67/548 scheduled on 23 January 2004 and to prevent irreparable negative business, financial and regulatory consequences for the applicants.

47 The applicants submit that the adoption and implementation of the Commission decision not to declassify rosin produces two types of adverse effects for which monetary awards could not provide an adequate compensation.

48 First, the Commission's failure to declassify rosin as a skin sensitiser results in a final and irreversible loss of confidence by customers in rosin and rosin-based products and therefore has an immediate adverse commercial impact on the applicants' products. The applicants submit that some of their customers manufacturing consumer products have active programs underway to replace rosin and rosin derivatives and that major consumer products manufacturers are in the process of phasing out the use of rosin ester-based adhesives by the middle

of 2004 in Europe. Likewise, the medical industry is excluding rosin-based resins from medical adhesives, such as plasters, because of the skin sensitisation potential EC regulatory authorities attribute to rosin. The applicants further explain that the use of and confidence in rosin is particularly sensitive to statements that the product presents a danger to human health and that even if those statements are subsequently disproved, it is virtually impossible to restore confidence in the product.

49 Another significant commercial impact resulting from the incorrect classification of rosin relates to the placement of rosin and rosin derivatives on user-restricted lists generated by certain leading companies and by certain countries. All of those lists place an obligation on suppliers and users alike to find alternative materials. The impact of being included on one of the user-restricted lists is instantaneous, resulting in inevitable losses of sales revenue. More importantly, the fact that inclusion on one of those lists results in rosin and rosin derivatives being excluded from new product formulations limits their commercial viability. Consequently, the loss in revenue may be gradual in the near term, but could and, according to the applicants' projections, will escalate rapidly in the coming years.

50 In addition, if the improper classification of rosin as a skin sensitiser is not rectified, or if the same classification is applied to rosin derivatives, then substitute raw materials will be chosen. However, the cost and performance characteristics of the replacement material are unfavourable to rosin. The applicants estimate that in the United States and European markets approximately 365 000 tons of rosin, in the form of derivatives, would be displaced. In addition, the rosin industry would be substantially over-supplied and the overall price for rosin going into all market applications would be greatly depressed.

51 Furthermore, even if the contested act were to be annulled by the Court of First Instance, the lost sales resulting from the contested act could not in practice be quantified completely for the purposes of making reparation, nor would they be recovered by the applicants.

52 Second, the applicants contend that the Commission's failure to declassify rosin establishes the classification standard for all rosin derivatives, with the consequence that the next logical step in the regulatory process will most likely be the classification of rosin derivatives as skin sensitisers. This would have enormous regulatory and financial implications for the applicants as all their rosin derivative products will be subject to classification on the same basis.

53 The contested act would also have a major impact on the markets for several products containing rosin, such impact being very difficult to reverse.

— Balance of interests

54 The applicants consider that the balance of the interests at stake leans in favour of the suspension of operation of the contested letter and the current entry for rosin in Annex I to Directive 67/548 because, first, the applicants would suffer serious and irreparable harm even though there is no scientific uncertainty about the properties of rosin and therefore no need to protect public health. Second, there is a need for the applicants and the Community at large to clarify some of the key criteria for the classification and labelling of chemical substances for purposes of legal certainty.

Arguments presented by the Commission

55 First, the Commission contends that the application is manifestly inadmissible because the applicants purport to impugn an act which is not reviewable, as the contested act does not affect their legal position.

56 Second, according to the Commission, as regards urgency, the applicants have adduced no evidence to the effect that their commercial survival is threatened by the classification of rosin in Annex I to Directive 67/548. The Commission submits that the size and breadth of activity of each of the applicants suggests that their survival does not turn on rosin and their success in that particular market. The Commission also contends that the fact that the applicants have lodged a claim for damages under Article 288 EC in the main action indicates that the applicants themselves consider that an award of damages could compensate them.

57 Finally, as regards the balance of the interests at stake, the Commission points out that a substantial reform of Directive 67/548 has been proposed to the Commission and that pending the adoption of such a reform the balance of interests militates against granting the interim measures requested.

Findings of the President

58 In the present case, without there being any need to decide whether the contested act produces legal effects which affect the applicants' interests, it must be considered whether the measures sought can be ordered by the judge hearing the application for interim measures and, *inter alia,* whether they could have any consequences of use to the applicants.

59 In their application, the applicants request, first, the suspension of the contested act, second, the suspension of the current entry for rosin under Annex I to Directive 67/548 and, third, an order directing the Commission to propose the declassification of rosin under the 29th adaptation to technical progress of Directive 67/548 at the next Regulatory Committee meeting.

60 Each of these forms of order must be examined separately.

61 As regards, first, the suspension of the contested act, based on the assumption that it constitutes a formal decision, it is not disputed that the act constitutes a negative decision.

62 In that light it should be noted that, in principle, there can be no application to suspend the operation of a negative administrative decision, since the granting thereof cannot have the effect of changing the position of the applicant (orders of the Court of Justice of 31 July 1989 in Case 206/89 R *S.* v *Commission* [1989] ECR 2841, paragraph 14, and of the President of the Court of Justice of 30 April 1997 in Case C-89/97 P(R) *Moccia Irme* v *Commission* [1997] ECR I-2327, paragraph 45).

63 In the present case, an order suspending the operation of the contested act could not have any consequences of use to the applicants as it could not amount to a positive decision proposing the declassification of rosin from Annex I to Directive 67/548.

64 Accordingly, this request must be rejected.

65 As regards next the applicants' requests that the President, first, suspend the operation of the current entry for rosin under Annex I to Directive 67/548 and, second, order the Commission to propose the declassification of rosin, it must be noted at the outset that those two measures would entail consequences much wider than the legal effects which might attach to success in the main action.

66 First, the request that the President suspend the operation of the current entry for rosin under Annex I to Directive 67/548 until such time as the Court of First Instance has given judgment in the main action, even though temporary, would have consequences *erga omnes*. By contrast, even assuming that the plea of illegality raised by the applicants in their main action against the current entry for rosin in Annex I to Directive 67/548 were admissible and successful, it could not lead to the annulment of the entry for rosin under Annex I to Directive 67/548, but only at most to the annulment of the contested act (see, to that effect, Case 9/56 *Meroni* v *High Authority* [1958] ECR 133, 140).

67 Second, as regards the applicants' request that the judge hearing the application for interim measures order the Commission to propose the declassification of rosin, it should be noted that a proposal to declassify rosin does not appear to be at this stage a necessary consequence of the annulment of the contested act and that it will be for the Commission to take the necessary measures to comply with the Court's judgment, in accordance with Article 233 EC. Accordingly, should the judge hearing the application for interim measures grant this request, it would amount to an injunction to draw precise inferences from the annulment decision, and such an order would exceed the Court's powers in the main action.

68 In addition, account must be taken of the fact that even if the judge hearing the application for interim measures granted the applicants' request, the proposal to declassify rosin would not automatically entail the declassification proposed, as there would be no guarantee that this proposal would be adopted without any modification at the closing of the legislative process set out by Article 29 of Directive 67/548. Thus, should this proposal be rejected, the order would have no useful effect for the applicants, as rosin would remain classified in Annex I to Directive 67/548.

69 Finally, the applicants have not demonstrated that the damage they rely on would be sufficiently foreseeable, serious and irreparable. In particular, the applicants have not adduced evidence establishing to the requisite legal standard that it is urgent to order interim measures.

70 As a preliminary matter, it must be noted that given the Commission's right to change the position expressed in the contested act before the next Regulatory Committee meeting scheduled for the adaptation of Directive 67/548 to technical progress, the premiss that the declassification of rosin from Annex I to this directive will not be proposed at the aforesaid meeting remains uncertain.

71 In addition, it must be borne in mind that the urgency of an application for interim relief must be assessed in the light of the need for an interlocutory order in order to avoid serious and irreparable damage to the party seeking the relief (order of the President of the Court of Justice of 18 November 1999 in Case C-329/99 P(R) *Pfizer Animal Health* v *Council* [1999] ECR I-8343, paragraph 94). Particularly where harm depends on the occurrence of a number of factors, it is enough for that harm to be foreseeable with a sufficient degree of probability (see, in particular, the order of the Court of Justice of 29 June 1993 in Case C-280/93 R *Germany* v *Council* [1993] ECR I-3667, paragraph 34, and the 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).

72 However, the applicant is still required to prove the facts which are deemed to attest to the probability of serious and irreparable damage (order in *HFB and Others* v *Commission* cited above at paragraph 71, paragraph 67, and order of the President of the Court of Justice of 12 October 2000 in Case C-278/00 R *Greece* v *Commission* [2000] ECR I-8787, paragraph 15).

73 In their application, the applicants contended that should the interim measures requested not be ordered, they could suffer two types of irreparable harm resulting, first, from commercial losses and, second, from future regulatory developments concerning rosin derivatives. These two risks must be assessed separately.

74 First, the applicants contend that if rosin remained listed in Annex I to Directive 67/548, their customers could lose confidence in this substance and stop using it to manufacture their own products. The damage resulting from this loss of confidence would therefore be of a financial nature.

75 In that respect, it has consistently been held that damage of a purely financial nature cannot, save in exceptional circumstances, be regarded as irreparable, or even as being reparable only with difficulty, if it can ultimately be the subject of financial compensation (order of the President of the Court of Justice of 18 October 1991 in Case C-213/91 R *Abertal and Others* v *Commission* [1991] ECR I-5109, paragraph 24; orders of the President of the Court of First Instance of 1 October 1997 in Case T-230/97 R *Comafrica and Dole Fresh Fruit Europe* v *Commission* [1997] ECR II-1589, paragraph 32, and of 15 June 2001 in Case T-339/00 R *Bactria* v *Commission* [2001] ECR II-1721, paragraph 94). This case-law is based on the premiss that damage of a financial nature that is not eliminated by the implementation of the judgment in the main proceedings constitutes an economic loss which may be made good by the means of redress provided for in the Treaty, in particular Articles 235 EC and 288 EC (order in *Comafrica and Dole Fresh Fruit Europe*, cited above, paragraph 38, and order 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 47).

76 In the circumstances of the present case, considering the risks alleged by the applicants, interim measures could be justified only if it appeared that, in the absence of such relief, the applicants would be placed in a situation which could endanger their very existence or irremediably affect their market share (see, by analogy, orders 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 138, and of 11 April 2003 in Case T-392/02 R *Solvay Pharmaceuticals* v *Council* [2003] ECR II-1825, paragraph 107).

77 It is therefore necessary to consider whether the applicants have demonstrated that they could suffer one of these two types of harm.

78 As regards, first, the risk related to an irremediable loss of market shares, the only piece of documentary evidence provided in that regard in the application for interim measures is an article that allegedly emanates from one of the applicants' customers. The article indicates that due to the fact that rosin or derivates from rosin can cause skin irritation, this customer cannot accept resins of natural origin. However, the applicants have specified neither the date of the article nor the importance of the company employing its author. Accordingly, the judge hearing the application for interim relief is not in a position to assess the actual significance of this customer for each of the applicants' businesses. In addition, there is nothing in the article to show that its author's opinion is linked formally to the classification of rosin in Annex I to Directive 67/548.

79 Furthermore, the applicants have provided no evidence describing their respective positions on the markets for rosin and its derivatives, nor did they sufficiently explain their argument that the classification of rosin in Annex I to Directive 67/548 and the related labelling requirements dramatically affect their respective customers' perceptions and habits.

80 At the hearing, the applicants explained for the first time that the loss of confidence and the commercial losses they rely on resulted from the combined application of Directive 67/548 and of the labelling requirements imposed by Directive 1999/45. The applicants referred in particular to point B(9) of Annex V to Directive 1999/45, cited at paragraph 14 above.

81 As rosin is classified as a sensitising substance in Annex I to Directive 67/548, it is possible that in certain circumstances the labels of the preparations containing rosin may have to mention that they contain a skin sensitiser.

82 However, the applicants have adduced no precise evidence allowing the judge hearing the application for interim measures to assess what proportion of their customers is actually concerned by such requirements and to what extent their habits and perception could be affected by them. Even at the hearing, the applicants made only general and vague allegations concerning clients that they did not name, thus preventing the judge hearing the application for interim measures from assessing the actual effect of the labelling requirements at issue.

83 Therefore, the applicants have not demonstrated the risk of a serious loss of market share.

84 In addition, even assuming that the applicants had demonstrated that they could lose a substantial proportion of their respective market shares, they have not proved that they would be confronted with obstacles of a structural or legal nature that could prevent them from regaining a significant proportion of those market shares following the introduction, in particular, of appropriate publicity measures (see, by analogy, order of the President of the Court of 11 April 2001 in

Case C-471/00 P(R) *Commission* v *Cambridge Healthcare* [2001] ECR I-2865, paragraph 111). It must therefore be concluded that the applicants have not established to the requisite legal standard that their market shares could be irremediably affected because of the operation of the contested act and of the application of Directive 67/548.

85 As regards, second, the risk that the applicants' existence could be jeopardized in the absence of the interim measures requested, it should be noted that such risk was formally invoked for the first time at the hearing.

86 In addition, it is apparent from paragraphs 78 to 83 above that the applicants have not demonstrated to the requisite legal standard that they could suffer serious commercial losses in the absence of interim relief.

87 In any case, where the applicant undertaking alleges that the negative impact on its financial viability would endanger its existence, consideration may be given, for the purposes of assessing its economic circumstances, to the characteristics of the group to which, by virtue of its shareholding structure, it belongs (orders of the President of the Court of Justice of 7 March 1995 in Case C-12/95 P *Transacciones Marítimas and Others* v *Commission* [1995] ECR I-467, paragraph 12, and of 15 April 1998 in Case C-43/98 P(R) *Camar* v *Commission and Council* [1998] ECR I-1815, paragraph 36).

88 In their application, the applicants have provided no evidence indicating what their respective financial sizes and situations are, while in its observations the Commission provided publicly available information tending to show that Arizona Chemicals, Eastman Belgium and Cray Valley Iberica each belong to large groups manufacturing a wide range of products. The applicants failed to rebut this evidence at the hearing.

89 As regards Resinall Europe, although it cannot be concluded on the basis of the evidence submitted by the Commission that this company belongs to a powerful group, it is apparent that its mother company is very active in North America. As there is no definite indication that the labelling requirements at issue are also applicable in that geographic area and Resinall Europe has not in any case demonstrated that these requirements could have a significant effect on its sales, it must be concluded that Resinall Europe has not demonstrated that its existence could be jeopardized in the absence of interim relief.

90 Finally, the applicants allege that the Commission's failure to declassify rosin establishes the classification standard for all rosin derivatives, with the consequence that the next logical step in the regulatory process will most likely be the classification of rosin derivatives as skin sensitisers, which could have deleterious effects in many industries.

91 However, the alleged damage remains, for the time being, entirely hypothetical in so far as it is based on the occurrence of future and uncertain events. Such damage cannot justify granting the interim measures requested (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).

92 More generally, the applicants have adduced nothing which would enable the judge hearing the application for interim measures to consider that, in the absence of interim measures, the applicants are likely to suffer irreversible damage which could not be made good if the contested act were to be annulled.

93 It follows that the applicants have not succeeded in proving the existence of circumstances giving rise to urgency which would establish a prima facie case for ordering interim measures.

94 Accordingly, without its being necessary to consider whether the applicants have demonstrated the existence of a prima facie case, 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, 16 January 2004.

H. Jung — B. Vesterdorf

Registrar — President