ORDER OF THE COURT OF FIRST INSTANCE (Third Chamber)
14 December 2005 *

In Case T-369/03,

Arizona Chemical BV, established in Huizen (Netherlands),

Eastman Belgium BVBA, established in Kallo (Belgium),

Resinall Europe BVBA, established in Bruges (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.

supported by

Republic of Finland, represented by T. Pynnä and A. Guimaraes-Purokoski, acting as Agents, with an address for service in Luxembourg,

intervener,

ACTION, first, for annulment of an act of the Commission rejecting the applicants' request for the withdrawal of rosin from the list of sensitising substances set out in 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, for compensation for the damages suffered,

THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES (Third Chamber),

composed of M. Jaeger, President, J. Azizi and E. Cremona, Judges,

Registrar: E. Coulon,

makes the following

Order

Law

1. *Relevant provisions of the EC Treaty*

1 Article 95 EC provides:

'1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

...

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on

scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

...'

2. *Classification as a dangerous substance*

2 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 inter alia 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'.

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

4 Article 4(1) of Directive 67/548 as amended ('Directive 67/548') 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).

5 Article 2(2) of Directive 67/548 provides that 'the following substances and preparations are "dangerous" within the meaning of this directive:

...

(k) sensitising substances and preparations: 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;

(l) carcinogenic substances and preparations: substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;

(m) mutagenic substances and preparations: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;

(n) substances and preparations which are toxic for reproduction: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity;

...'

6 Article 4(2) states that 'the general principles of the classification and labelling of substances and preparations shall be applied according to the criteria in Annex VI, save where contrary requirements for dangerous preparations are specified in separate directives'.

7 Article 4(3) states:

'Annex I contains the list of substances classified in accordance with the principles outlined in paragraphs 1 and 2, together with their harmonised classification and labelling. The decision to place a substance in Annex I together with the harmonised classification and labelling shall be taken in accordance with the procedure laid down in Article 29.'

8 Classification of a substance as 'dangerous' requires appropriate labelling on the package as a precondition for sale, 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 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 ...'.

9 Section 1.1 of Annex VI to Directive 67/548 states:

'The object of classification is to identify all the physico-chemical, toxicological and ecotoxicological properties of substances and preparations which may constitute a risk during normal handling or use. Having identified any hazardous properties, the substance or preparation must then be labelled to indicate the hazard(s) in order to protect the user, the general public and the environment.'

10 Section 1.7.2, third paragraph, of Annex VI provides:

'Without prejudice to Article 6, where the above procedure has been followed and there is concern over possible inconsistencies then a proposal may be submitted for the entry of the provisional classification into Annex I. The proposal should be made to one of the Member States and should be accompanied by appropriate scientific data (see also section 4.1).'

11 Section 4.1.2 of Annex VI provides:

'If a manufacturer, distributor or importer has information available which indicates that a substance should be classified and labelled in accordance with the criteria

given in section 4.2.1, 4.2.2 or 4.2.3, he shall provisionally label the substance in accordance with these criteria, on the basis of the assessment of the evidence by a competent person.'

12 According to section 4.1.3, 'the manufacturer, distributor or importer shall submit as soon as possible a document summarising all relevant information to one Member State in which the substance is placed on the market'.

13 Section 4.1.4 states as follows:

'Furthermore, a manufacturer, distributor or importer who has new data which are relevant to the classification and labelling of a substance in accordance with the criteria given in section 4.2.1, 4.2.2 or 4.2.3 shall submit this data as soon as possible to one Member State in which the substance is placed on the market.'

14 Section 4.1.5 states as follows:

'To obtain as quickly as possible a harmonised classification for the Community by the procedure defined in Article 28 of this Directive, Member States which have relevant information available justifying the classification of a substance in one of these categories, whether submitted by the manufacturer or not, should forward such information, together with suggestions for classification and labelling, to the Commission as soon as possible.

The Commission will forward to the other Member States the classification and labelling proposal that it receives. Any Member State may ask the Commission for the information it has received.

...'

15 Sections 4.2.1, 'Carcinogenic substances', 4.2.2, 'Mutagenic substances' and 4.2.3, 'Substances toxic to reproduction', of Annex VI set out the harmful characteristics of the dangerous substances referred to in Article 2(2)(l) to (n) and divide them into three categories on the basis of their actual or suspected dangerousness.

16 Lastly, Article 14(1) of Directive 67/548 imposes additional obligations on any notifier of a substance already notified to inform the relevant national authorities. Article 14(2) requires importers to ensure that certain requirements are met by a manufacturer established outside the Community and by his sole representative who has imported and notified the substance in question in accordance with Article 2(1)(d).

3. *Adaptation of Directive 67/548 to technical progress*

17 Article 28 of Directive 67/548 provides:

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

18 In practice the Commission, when it first works on an initial draft of measures adapting Directive 67/548 to technical progress, consults the Working Group on Classification and Labelling ('the Working Group'). That group comprises experts sent by the Member States such as toxicologists and classification experts, representatives of the chemical industry and representatives of the particular branch of the industry concerned by the products under discussion. After consulting the Working Group, the Commission submits the draft measures to the committee established by Article 29 of Directive 67/548 ('the Regulatory Committee').

19 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.'

20 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) provides, under the heading 'Regulatory procedure', 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) [EC] 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 [EC] 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.'

21 Directive 67/548 does not lay down specific provisions for the purposes of the declassification of a substance which no longer satisfies the relevant criteria of dangerousness. However, Article 5 of Directive 67/548 on the 'Duties of the Member States' provides in paragraph 2 that certain necessary measures adopted by the Member States 'shall apply until the substance is listed in Annex I or until a decision not to list it has been taken in accordance with the procedure laid down in Article 29'.

Facts and procedure

22 The applicants manufacture and sell rosin and rosin derivatives.

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

24 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'.

25 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 withdrawn from Class R 42. Rosin remained, however, listed in Annex I as an inhalation sensitiser with the risk phrase R 43: 'may cause sensitisation by skin contact'. The product label must bear the symbol Xi 'irritant' and the phrases S 2 'Keep out of the reach of children', S 24 'Avoid contact with skin' and S 37 'Wear suitable gloves'. According to the first subparagraph of Article 2 of Directive 94/69, not later than 1 September 1996 the Member States are to implement the laws, regulations and administrative provisions necessary to comply with that directive. That classification is still in force.

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

27 At its meeting of October 1999 the 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'.

28 In September 2002, the 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 de-classified for sensitising properties and not further discussed on the basis of current data'.

29 On 23 June 2003, the applicants sent a letter to the Commission requesting that it take such measures as were necessary to declassify rosin as a skin sensitiser.

30 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 10" allergens'. The contested act concludes that the applicants have not provided 'appropriate reasons to declassify rosin'.

31 By application lodged at the Registry of the Court of First Instance on 29 October 2003, the applicants brought this action claiming that the Court should:

— annul the contested act;

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

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

— order the defendant to pay damages in compensation for the loss resulting from the adoption of the contested act;

— order the defendant to pay the costs.

32 By separate document lodged at the Court Registry on 27 November 2003, the applicants brought an application for interim measures under Articles 242 EC and 243 EC. By order of 16 January 2004 in Case T-369/03 R *Arizona Chemical and Others* v *Commission* [2004] ECR II-205, the President of the Court of First Instance dismissed that application.

33 By separate document lodged at the Court Registry on 4 February 2004, the defendant applied for a decision on admissibility under Article 114 of the Rules of Procedure of the Court of First Instance. The applicants lodged their observations on that application on 12 March 2004.

34 By application registered at the Court Registry on 12 March 2004, the Republic of Finland sought leave to intervene in the present proceedings in support of the form of order sought by the defendant.

35 By order of 16 July 2004, the President of the Third Chamber of the Court of First Instance decided in favour of the application to intervene. The intervener lodged its statement in intervention on 15 September 2004.

Law

36 Under Article 114(1) of the Rules of Procedure, if a party so requests, the Court may make a decision on admissibility without considering the substance. Under Article 114(3), unless the Court otherwise decides the remainder of the proceedings are to be oral. The Court finds that in the present case it has sufficient information from the case-file not to open the oral procedure.

37 The defendant's application for a decision on admissibility covers the application for annulment of the contested act, the claim for damages and lastly the plea of illegality raised by the applicants under Article 241 EC.

1. *The admissibility of the application for annulment of the contested act*

Arguments of the parties

38 The defendant, supported by the intervener, submits that the application for annulment of the contested act is inadmissible.

39 As a preliminary point the applicants ask the Court, relying on Article 114(4) of the Rules of Procedure, to proceed directly to consider the substance of the case in accordance with the case-law (Joined Cases 126/75, 34/76 and 92/76 *Giry* v *Commission* [1977] ECR 1937; Joined Cases 193/82 to 198/82 *Rosani and Others* v *Council* [1983] ECR 2841; Case 64/82 *Tradax* v *Commission* [1984] ECR 1359; and Case C-57/95 *France* v *Commission* [1997] ECR I-1627, paragraphs 9 and 10)

because of the peculiar complexity of the legislation in question and their legal situation. In the alternative they ask the Court, pursuant to Article 114(3) of the Rules of Procedure, to order that the remainder of the proceedings relating to the plea of inadmissibility be oral and to fix a date for the hearing. In any event, according to the applicants, it follows from the principle of legality and the right to an effective legal remedy that the Court of First Instance, as 'the Court of last resort' in this case, should address the substance of the dispute.

40 The applicants submit that the application for annulment is admissible under Article 230(4) EC because the contested act, signed by a Director, was addressed directly to them and lays down the defendant's definitive and official position towards their 'precise and formal' request. In that context, according to settled case-law, the particular form in which the act was adopted is immaterial and it is its substance which must be examined so far as concerns the possibility of its being challenged by an action for annulment. Moreover, the definitive nature of the contested act cannot be called in question merely on the ground that the request was considered only by the Commission's staff (order of 4 May 1998 in Case T-84/97 *BEUC* v *Commission* [1998] ECR II-795, paragraph 48). The applicants further submit that, as the addressees of the contested act, they do not have to show that they are 'directly and individually concerned' within the meaning of the fourth paragraph of Article 230 EC.

41 Furthermore, according to the applicants the contested act cannot be regarded as a purely provisional or legislative measure which is not challengeable by an action for annulment. It is administrative in nature and produces binding legal effects in that it definitively lays down the position of the defendant with regard to the application for declassification and the relevant data which they submitted in support, by dismissing that application and thus bringing to an end the administrative procedure for the assessment of rosin (Case 60/81 *IBM* v *Commission* [1981] ECR 2639, paragraph 10, and Case T-64/89 *Automec* v *Commission* [1990] ECR II-367, paragraph 42). In the context of the powers conferred upon it by Directive 67/548, the Commission carries out an administrative assessment with the help of the Working Group and

undertakings in the industry whose participation, by the supply of data and because of their know-how and expertise with regard to the goods in question, is indispensable.

42 Furthermore, the defendant errs in submitting that the applicants play no role in the classification procedure, as the Commission itself expressly admitted in its report on the operation of Directive 67/548 that 'harmonised classification and labelling is undertaken by a working group of Commission and Member State experts with the participation of industry' and that 'the industrial chemicals for discussion are proposed by Member States and to a lesser extent by industry'. According to the applicants, the defendant also misinterprets the scope of Article 14 of Directive 67/548, which requires the applicants to inform the relevant authorities of 'new knowledge ... of which [they] may reasonably be expected to have become aware'. In the present case, the applicants actively participated for more than 10 years in the administrative procedure for the assessment of rosin by submitting data and observations.

43 It follows that in order correctly to classify rosin, the Commission was required carefully and impartially to assess the evidence which the applicants had submitted to them (Case C-269/90 *Technische Universität München* [1991] ECR I-5469, and Case T-54/99 *max.mobil* v *Commission* [2002] ECR II-313). Furthermore, according to the Court's case-law (Case C-358/89 *Extramet Industrie* v *Council* [1991] ECR I-2501), 'an undertaking should have standing to challenge regulations where ... it played an important part in the procedure leading to the adoption of the regulation'.

44 The applicants add that, contrary to what the defendant alleges, they did not 'initiate' the legislative process of adaptation to technical progress. The contested act is not a proposal within the meaning of the order of 15 May 1997 in Case T-175/96 *Berthu* v *Commission* [1997] ECR II-811, because in the present case the Commission has not proposed anything. It has decided that rosin will not be

declassified and, on that basis, has closed the administrative review of rosin without even preparing a formal proposal on rosin. The applicants consider more particularly that in the absence of a proposal to declassify rosin pursuant to the procedure laid down in Article 29 of Directive 67/548, the Regulatory Committee cannot act ultra petitum and carry out such adaptation. That shows that the defendant's decision not to propose that rosin be declassified is a definitive decision. Similarly, that decision, to which the contested act refers, constitutes a definitive measure in relation to the applicants.

45 According to the applicants, the contested act is comparable to a comfort letter or a decision to reject a complaint in Community competition law (Case 210/81 *Demo-Studio Schmidt* v *Commission* [1983] ECR 3045; Joined Cases 142/84 and 156/84 *BAT and Reynolds* v *Commission* [1987] ECR 4487; Case C-39/93 *SFEI and Others* v *Commission* [1994] ECR I-2681; Case T-241/97 *Stork Amsterdam* v *Commission* [2000] ECR II-309; and *max.mobil* v *Commission*, paragraph 43 above) or a decision — open to challenge because it produces definitive legal effects — to open a State aid procedure under Article 88(2) EC (Case C-47/91 *Italy* v *Commission* [1992] ECR I-4145; Case C-312/90 *Spain* v *Commission* [1992] ECR I-4117; Joined Cases T-126/96 and T-127/96 *BFM and EFIM* v *Commission* [1998] ECR II-3437).

46 Since the present action is directed against a decision to reject a complaint, the obligation to consider that complaint carefully and impartially flows from a general principle of Community law, recognised in Article 41(1) of the Charter of Fundamental Rights of the European Union proclaimed at Nice on 7 December 2000 (OJ 2000 C 364, p. 1), which provides that 'every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union'. The Commission's obligation to undertake a diligent and impartial examination of all the evidence and submissions of law and fact which complainants have referred to it has been recognised in the case-law on Community competition and State aid law (see *BAT and Reynolds* v *Commission*, paragraph 45 above, paragraph 20; Case C-449/98 P *IECC* v *Commission* [2001] ECR

I-3875, paragraph 45; Case T-24/90 *Automec* v *Commission* [1992] ECR II-2223, paragraph 79; Case T-95/96 *Gestevisión Telecinco* v *Commission* [1998] ECR II-3407, paragraph 53; and *max.mobil* v *Commission*, paragraph 43 above). According to the applicants, the plea of inadmissibility should be rejected 'on the basis of [the judgment in] *max.mobil* alone', paragraph 43 above (paragraph 71), since they are the addressees of the contested act which dismisses their complaint and the Court must exercise its power of review as to whether the Commission properly examined that complaint.

47 The applicants submit that Article 95 EC gives rise analogously to a legitimate expectation that any measure regarding public health, such as the classification of rosin as a skin sensitiser, be based on state-of-the-art information taking into account 'any new development based on scientific facts', and that the fulfilment of the Commission's obligation to undertake a diligent and impartial examination must be amenable to judicial review (*max.mobil* v *Commission*, paragraph 43 above, paragraph 56), regardless of the form of the measure by which the Commission terminates the administrative assessment process, to the extent that the measure produces binding legal effects and is such as to affect the interests of an applicant by bringing about a distinct change in his legal position (Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571, paragraphs 49 and 55). In the present case the interests of the applicants are so affected and their legal position is so changed because of the decisive nature of the contested act regarding the classification of rosin and because that act affects their products.

48 The applicants submit lastly that the annulment of the contested act would have the legal consequence of obliging the Commission to take such measures as are necessary to comply with the judgment and therefore to declassify rosin as requested by the applicants (Case 53/85 *AKZO Chemie* v *Commission* [1986] ECR 1965, paragraph 21; Case 207/86 *Apesco* v *Commission* [1988] ECR 2151, paragraph 16; and Case T-46/92 *Scottish Football* v *Commission* [1994] ECR II-1039, paragraph 14), which demonstrates that the applicants have a legitimate interest in having the Court clarify the conditions in which the Commission is obliged to propose such a declassification.

Findings of the Court

Preliminary observations

49 As a preliminary point, the Court considers it necessary to place the applicants' initial request leading to the adoption of the contested act in its factual and legal context.

50 In that respect, the Court notes in the first place that the applicants' request to the Commission that rosin be declassified occurred in the context of the adaptation of Directive 67/548 to technical progress and, therefore, of a procedure resulting in the adoption of measures of general application.

51 First, not only is the procedure leading to the classification or declassification of a substance in Annex I of Directive 67/548 laid down by Article 29 of Directive 67/548, by Regulation No 807/2003 and by Article 5 of Decision 1999/468 a complex one which results in the adoption of measures of general application, comparable to a 'comitology' procedure, but the latter provision is also expressly described as the 'Regulatory procedure'. Under that procedure, the Commission enjoys, first of all, a power of initiative as part of the legislative process, introducing any draft amendment of the annexes to Directive 67/548 for transmission to the Regulatory Committee, which is composed essentially of representatives of the Member States and on which the presiding Commission representative may not vote, for its opinion (Article 5(2), final sentence, of Decision 1999/468). Next, in order to ensure the efficacy of the adaptation to technical progress, the Commission may exercise a regulatory power, inasmuch as it can adopt the measures envisaged if they are in accordance with the opinion of the Regulatory Committee (Article 5(3) of Decision 1999/468). If there is no opinion sanctioning them, the Commission must submit to the Council a proposal relating to the measures to be taken and must

inform the Parliament (Article 5(4) of Decision 1999/468), as that procedure may in certain circumstances cause the Commission to present a 'legislative proposal on the basis of the Treaty' (Article 5(6) second subparagraph of Decision 1999/468). It follows that in the context of the abovementioned procedure, Decision 1999/468 confers on the Commission a specific role in the drafting of measures of general application.

52 Second, decisions to classify or declassify products are by virtue of their content of general application inasmuch as, regarded generally and in the abstract, they apply to objectively determined situations and entail legal effects for a host of traders currently carrying on a business relating to the marketing of products containing the substances in question or intending to do so in the future.

53 The Court notes secondly that it is not in dispute between the parties that the contested act is a refusal on the part of the Commission addressed to the applicants to propose to the Regulatory Committee a draft amendment of Directive 67/548 on its 29th adaptation, as sought by the applicants. It is also clear that the proposal for an amendment sought by the applicants' request was thus a provisional and preparatory act in the context of the procedure adapting Directive 67/548 to technical progress, prior to the adoption of the amendment to the directive the content of which would not necessarily correspond to that of the initial proposal.

54 It is in the light of those findings that the arguments of the parties should be assessed.

The legal nature of the contested act

— Preliminary observations

55 The contested act is a letter from the Commission signed by a director and addressed to the applicants in reply to their application for the Commission to propose to the Regulatory Committee that rosin be declassified in the 29th adaptation of Directive 67/548. In the light of its particular legal nature, it is necessary to consider whether that letter may be treated as a decision, open to challenge by an individual, within the meaning of the fourth paragraph of Article 230 EC.

56 It should be noted in that regard that according to the case-law it is not sufficient that a letter was sent by a Community institution to its addressee in reply to a request made by that addressee for it to qualify as a decision for the purposes of Article 230 EC. According to settled case-law, the only measures against which an action for annulment may be brought under Article 230 EC are those which have binding legal effects capable of affecting the interests of the applicant by bringing about a distinct change in his legal position (Case C-257/90 *Italsolar* v *Commission* [1993] ECR I-9, paragraph 21; the orders of 4 October 1996 in Case T-5/96 *Sveriges Betodlares and Henrikson* v *Commission* [1996] ECR II-1299, paragraph 26, and 11 December 1998 in Case T-22/98 *Scottish Soft Fruit Growers* v *Commission* [1998] ECR II-4219, paragraph 34; Case T-83/92 *Zunis Holding and Others* v *Commission* [1993] ECR II-1169, paragraph 30). Furthermore, the form in which the contested act was adopted is in principle immaterial so far as concerns the analysis of its legal effects, which should primarily be examined in relation to the substance of the act (orders in *BEUC* v *Commission*, paragraph 40 above, paragraph 48, and *Berthu* v *Commission*, paragraph 44 above, paragraph 19).

57 In the present case, the applicants put forward essentially three arguments. First, they submit that their request and its rejection by the contested act fall within the

scope of an 'administrative' framework rather than a 'legislative' one. That is because the Commission was required, in close cooperation with the Working Group and industry representatives, for the purposes of the correct classification of rosin according to its intrinsic characteristics and on the basis of information provided by operators including the applicants, to carry out an examination in accordance with the principles and criteria laid down by Directive 67/548. Second, the contested act refusing to declassify rosin is the Commission's definitive position with regard to the applicants and thus concludes the administrative phase of the decision-making process since, in the absence of a proposal from the Commission to that effect, the Regulatory Committee could not grant the declassification sought. Third, the applicants compare the treatment of their request to that of a complaint in competition law and conclude that the contested act is comparable to a decision rejecting a complaint, or a comfort letter, and therefore produces definitive and binding legal effects on them. In this context, the applicants refer in particular to the case-law indicating that the Commission was required diligently and impartially to examine their 'complaint'.

— The allegedly administrative and individual nature of the examination of the intrinsic properties of the substances

58 First, it should be stated that the applicants' arguments are based on the assertion that the procedures and measures adopted in the context of the adaptation of Directive 67/548 to technical progress are administrative in that they are intended to result in the adoption of acts of individual application. As was noted in paragraphs 50 to 53 above, the procedure for the adaptation of that directive to technical progress, in both form and outcome, is a procedure resulting in the adoption of measures of general application.

59 Second, the Court finds that the applicants cannot validly maintain that the preliminary phase of the examination of the intrinsic properties of the substances is

'administrative'. It is true that that preliminary phase of the examination — which is not subject to express rules — precedes the proposal to classify or declassify which triggers the decision-making process proper laid down by Article 29 of Directive 67/548. It also falls within the sole competence of the Commission which, in close cooperation with the Working Group composed of national experts, including industry representatives, bases its assessment to a large extent on the data and studies submitted by the operators and their associations in the industry in question. Nevertheless, that is not sufficient to support the conclusion that that preliminary phase of the assessment is comparable to the assessment procedures leading to the adoption of acts of individual application, applying to certain products and certain economic operators, such as exist inter alia in competition law and the law of external trade. Unlike the various phases — even preliminary — of the procedure for the adaptation of Directive 67/548 to technical progress, the purpose of those procedures is in general to adopt measures of individual application, which also justifies the grant of procedural guarantees to the operators in question. Anti-dumping procedures are similar in several respects, notwithstanding the fact that they result in the adoption of regulations of general application, because, according to the case-law, those procedures are administrative as they are particularly likely to distinguish certain undertakings individually and they lay down procedural guarantees in favour of those undertakings (see to that effect Case C-76/01 P *Eurocoton and Others* v *Council* [2003] ECR I-10091, paragraph 69 et seq.).

60 In the present case, those criteria are clearly not met. The preliminary procedure for the assessment of the intrinsic properties of the substances in question, far from being directed at the individual interests of the operators in question or preparing an individual decision applicable to them, is merely the phase preceding the preparation of a measure of general application, namely a proposal to amend a directive, as provided for by Article 29 of Directive 67/548. Furthermore, the fact that, when the Commission and the Working Group draft proposals to be submitted to the Regulatory Committee, they take account of the information and data provided by the industry for the purposes of the classification or declassification of substances, likewise does not suffice to make the preliminary assessment procedure of individual concern.

61 In the light of the foregoing, the preliminary assessment procedure carried out by the Commission and the Working Group cannot be dissociated from the framework in which it takes place and its purpose. It follows that the applicants' argument on that point cannot be upheld.

— The allegedly administrative and definitive nature of the Commission's refusal and the applicability of the case-law on the rejection of complaints or comfort letters in the field of competition

62 It follows from the findings set out above that the applicants' argument that the contested act is a definitive act of an administrative nature cannot be upheld.

63 Moreover, that argument amounts essentially, and contrary to the principles laid down by the case-law cited in paragraph 56 above, to giving individuals the ability to change the procedure which led to the adoption of measures of general application amending Directive 67/548 into a procedure of individual concern, by sending the Commission a written request to which that institution is required to respond pursuant to the general rule of good conduct laid down by the third paragraph of Article 21 EC. It should be noted that even if such a response were definitive it would not alter the legal nature of the procedure leading to the classification or declassification of substances nor would it alone be sufficient to confer standing on the recipient.

64 Furthermore, it is settled case-law that an act of the Commission which amounts to a rejection must be appraised in the light of the nature of the request to which it constituted a reply (Joined Cases C-15/91 and C-108/91 *Buckl and Others* v *Commission* [1992] ECR I-6061, paragraph 22). In particular, a Community institution's refusal to withdraw or amend an act is only in itself an act the legality

of which can be reviewed under Article 230 EC where the act which the Community institution refuses to withdraw or amend could itself be challenged under that provision (Case 42/71 *Nordgetreide* v *Commission* [1972] ECR 105, paragraph 5; Joined Cases 97/86, 99/86, 193/86 and 215/86 *Asteris and Others* v *Commission* [1988] ECR 2181, paragraph 17; Case C-87/89 *Sonito and Others* v *Commission* [1990] ECR I-1981, paragraph 8; *Zunis Holding and Others* v *Commission*, paragraph 56 above, paragraph 31; and the order in *Scottish Soft Fruit Growers* v *Commission*, paragraph 56 above, paragraph 41).

65 It follows that in the present case the contested act rejecting the applicants' request cannot be assessed independently of the act expressly referred to by that request, namely the proposal to amend Directive 67/548. Accordingly, the contested act is only an act amenable to review if the proposed amendment sought and the classification of rosin in Annex I of Directive 67/548 were also capable of being the subject of an action for annulment brought by the applicants.

66 It must be observed that the applicants' request for a proposal to amend Directive 67/548 is likewise not a reviewable act under Article 230 EC, because it is merely preliminary and preparatory in nature. According to settled case-law concerning acts or decisions drafted in several stages, in principle only measures definitively laying down the position of the institution concerned on the conclusion of that procedure may be the subject of an action for annulment, so that intermediate measures which serve to prepare for the final decision are excluded (see the order in *Berthu* v *Commission*, paragraph 44 above, paragraph 19, and the case-law cited, and the order of 2 June 2004 in Case T-123/03 *Pfizer* v *Commission* [2004] ECR II-1631, paragraph 22 et seq.). However, notwithstanding the fact that the contested act is the Commission's definitive response to the applicants' request, it is merely a position adopted in relation to a purely preliminary and preparatory measure which thus as such is not open to an action for annulment. A fortiori therefore, in the light of the case-law cited in paragraph 64 above, the contested act is not an act open to review within the meaning of Article 230 EC.

67 Moreover, the conditions for admissibility of any action by the applicants to challenge the classification of rosin in Annex I to Directive 67/548 are clearly not met in the present case. It is true that according to settled case-law even a measure of general application may, in certain circumstances, be of direct and individual concern to certain individuals or economic operators provided that it identifies them by reason of certain attributes which are peculiar to them or by a factual situation which distinguishes them from all other persons (order of 12 March 1998 in Case T-207/97 *Berthu* v *Council* [1998] ECR II-509, paragraph 23 and the case-law cited). However, in this case the applicants have not even attempted to demonstrate that they were directly and individually concerned within the meaning of the fourth paragraph of Article 230 EC by any amendment to Directive 67/548, and in particular by any classification or declassification of rosin. On the contrary, the applicants asserted that, as the addressees of the contested act, they did not have to show that they were directly and individually concerned within the meaning of the fourth subparagraph of Article 230 EC.

68 In that context the applicants' argument based on the case-law relating to the admissibility of actions brought against decisions to open a detailed investigation procedure under Article 88(2) EC (see paragraph 45 above) must also be rejected. That case-law cannot be applied to the present case because, first, the review procedures in relation to State aid, unlike the procedure in question in the present case, apply to the adoption of an individual administrative act and not an act of general application (see paragraph 59 above). Second, the case-law in relation to State aid concerns primarily relations between the Commission and the Member State. Therefore that case-law relates principally to the particular legal effects on Member States — and to a lesser degree on individuals — of the provisional classification by the Commission of a State measure as new aid within the meaning of Article 88(3) EC. Third, a refusal by the Commission to propose the declassification of a substance has nothing in common with a decision to open such a detailed investigation in relation to State aid, which is, moreover, likely to lead to the outcome sought by the complainant.

69 It follows from the foregoing that the applicants' argument that the contested act is administrative, individual and definitive must be rejected.

70 Lastly, the applicants' argument that the case-law relating to the rejection of complaints and comfort letters in the field of competition law is applicable to the present case must also be rejected. That case-law does not relate to the participation of individuals in the procedure leading to the adoption or amendment of directives. In the case of procedures leading to the adoption of measures of general application, it is only in exceptional cases that the case-law has recognised a right of action for an individual 'applicant' or 'complainant', in particular where he enjoys procedural guarantees expressly laid down by the legislation in question (see paragraphs 72 and 73 below).

71 Therefore, it is necessary at this stage to consider whether, in the context of the procedure for the adaptation of Directive 67/548 to technical progress, the applicants enjoyed procedural guarantees capable of rendering the present action admissible.

The existence of procedural guarantees in favour of individuals in the context of the procedure for the adaptation of Directive 67/548 to technical progress

— Preliminary observations

72 As a preliminary point, the case-law should be recalled according to which the fact that a person is involved in some way or other in the procedure leading to the adoption of a Community measure is capable of distinguishing that person individually in relation to the measure in question, which must mean that the measure has binding legal effects for him, only if the applicable Community legislation grants him certain procedural guarantees (see, to that effect, Case T-47/00 *Rica Foods* v *Commission* [2002] ECR II-113, paragraph 55; Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 101; Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraph 93; and the orders of 29 April 2002 in Case T-339/00 *Bactria* v *Commission* [2002] ECR II-2287, paragraph 51, and Case T-142/03 *Fost Plus* v *Commission* [2005] ECR II-589, paragraph 61 et seq.).

73 It is also settled case-law that in principle, according to the general principles of Community law such as the right to a hearing, neither the process of enacting acts of general application nor the nature of those acts themselves require the participation of the persons affected as the interests of those persons are deemed to be represented by the political bodies called to adopt those acts (see, to that effect, the orders of 15 September 1998 in Case T-109/97 *Molkerei Großbraunshain and Bene Nahrungsmittel* v *Commission* [1998] ECR II-3533, paragraph 60, and 9 November 1999 in Case T-114/99 *CSR Pampryl* v *Commission* [1999] ECR II-3331, paragraph 50). Consequently, in the absence of expressly guaranteed procedural rights it would be contrary to the letter and spirit of Article 230 EC to allow any individual, once he has participated in the preparation of an act of a legislative nature, to then bring an action challenging that act (orders in *Molkerei Großbraunshain and Bene Nahrungsmittel* v *Commission*, paragraph 68, *CSR Pampryl* v *Commission*, paragraph 50, and the order of 30 January 2001 in Case T-215/00 *La Conqueste* v *Commission* [2001] ECR II-181, paragraph 42, confirmed by the order of 30 January 2002 in Case C-151/01 P *La Conqueste* v *Commission* [2002] ECR I-1179, paragraph 42 et seq.).

74 Moreover, as regards more particularly an area related to that governed by Directive 67/548, namely that of cosmetic products, governed by Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ 1976 L 262, p. 169), as amended in particular by Council Directive 93/35/EEC of 14 June 1993 (OJ 1993 L 151, p. 32), the Court has held that whilst the adversarial principle is a fundamental principle of Community law which applies in all administrative proceedings initiated against a particular person which are liable to culminate in a measure adversely affecting that person, it does not ordinarily arise in proceedings resulting in the adoption of measures of general application (see Case T-199/96 *Bergaderm and Goupil* v *Commission* [1998] ECR II-2805, paragraph 58 and the case-law cited). However, it is only in exceptional circumstances that express provision is made for the participation of third parties in such proceedings. That is the case inter alia in anti-dumping proceedings, in which some rights of the defence expressly provided for must be guaranteed in adopting measures of general application (*Bergaderm and Goupil* v *Commission*, paragraph 59; orders in *Molkerei Großbraunshain and Bene Nahrungsmittel* v *Commission*, paragraph 73 above, paragraph 69, and of 30 January 2001 in Case T-215/00 *La Conqueste* v *Commission*, paragraph 73 above, paragraph 46).

75 In the light of that case-law it is necessary, first of all, to consider whether Directive 67/548 expressly confers procedural guarantees on the operators in question. Next, the Court finds it necessary to consider whether the applicants may exceptionally, in the particular legal context of the present case, invoke implied procedural guarantees resulting from a general principle of law.

— The existence of express procedural guarantees in the context of the procedure for the adaptation of Directive 67/548 to technical progress

76 It should be noted that Directive 67/548 contains no provision conferring on economic operators in the applicant's situation the power to initiate the adaptation procedure in question, nor does it lay down any rule requiring the Commission, before presenting an adaptation proposal, to follow a procedure in which those operators enjoy procedural guarantees.

77 Although section 1.7.2, third subparagraph, of Annex VI to Directive 67/548 states that where they have new information manufacturers, importers or distributors may submit a proposal to the relevant authorities of a Member State for the amendment of Annex I, that can occur only in the context of relations between the economic operator in question and the Member State. Accordingly, at Community level it lays down neither the power of those operators to initiate the procedure nor a procedural guarantee in their favour, such as the right to be heard (see, to that effect, the order of the President of the Court of First Instance of 10 February 2005 in Case T-291/04 R *Enviro Tech Europe and Enviro Tech International* v *Commission* [2005] ECR II-475, paragraph 68, and, concerning a similar situation, the order in *Bactria* v *Commission*, paragraph 72 above, paragraph 51, confirmed by the order of 12 December 2003 in Case C-258/02 P *Bactria* v *Commission* [2003] ECR I-15105, paragraphs 43 and 44).

78 Similarly, sections 4.1.3, 4.1.4 and 4.1.5 of Annex VI to Directive 67/548 require the operators to notify information relating to classification only to the Member States. The obligation on the Commission under section 4.1.5, second paragraph, of Annex VI to Directive 67/548 to inform the other Member States merely concerns any proposal for classification sent by the Member State to which that information is sent and not the information as such, as that is only sent to the other Member States at their express request. Moreover, those obligations concern only particularly dangerous substances expressly referred to in sections 4.2.1 to 4.2.3, not including sensitising substances such as rosin. Lastly, Article 14 of Directive 67/548, which the applicants cite in that context, only imposes an obligation to notify on operators in a situation which bears no resemblance to that of the applicants in the present case.

79 Neither the letter nor the spirit of those provisions indicates that those obligations entail the attribution of certain procedural guarantees at Community level. Without its being necessary to consider whether any procedural guarantees are accorded by the Member States, it must be found that the duties to inform referred to above, in particular in relation to particularly dangerous substances, fully and objectively pursue a public policy objective, namely the attainment of the general objectives of the protection of health, safety and the environment, on the basis of the latest information on dangerous substances, by the effective and uniform implementation of Directive 67/548. That is confirmed by the objective set out in section 4.1.5, first paragraph, of Annex VI to Directive 67/548 'to obtain as quickly as possible a harmonised classification for the Community by the procedure defined in Article 28 of this Directive'.

80 It follows that those provisions do not create a procedural guarantee at Community level in favour of the economic operators concerned so as to render the present action admissible (see, to that effect, the order of 30 January 2001 in Case T-215/00 *La Conqueste* v *Commission*, paragraph 73 above, paragraphs 44 to 49, confirmed by the order of 30 January 2002 in Case C-151/01 P *La Conqueste* v *Commission*, paragraph 73 above, paragraph 42 et seq.).

81 For the sake of completeness, it should be pointed out that the provisions in question are clearly distinguishable from those of the Community scheme of generalised tariff preferences at issue in the *DuPont* case (Case T-113/00 *DuPont Teijin Films Luxembourg and Others* v *Commission* [2002] ECR II-3681, paragraphs 47 to 55) in so far as the latter lay down an unconditional obligation on the Community administration to act on information provided by an operator, with a corresponding procedural guarantee in favour of the operator, compliance with which must be subject to effective judicial review. Similarly, the applicants' situation cannot be compared to that at issue in *Pfizer Animal Health* v *Council* and *Alpharma* v *Council* (paragraph 72 above), in which the Court held that, although the procedure laid down in Article 24 of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ, English Special Edition 1970 (III), p. 840) did not as such confer a right of participation on the operators concerned, account should nevertheless be taken of the fact that the applicant, as the applicant under Article 9g(2) and (4) of Directive 70/524, had itself given rise to the procedure governed by Article 4 of that directive. That article expressly provides that the decision-making process is initiated at the request of the operator in question and also, unlike the provisions governing the procedure at issue in the present case, confers on that person procedural guarantees such as the right to be notified throughout the various stages of that procedure if the application does not comply with the relevant provisions, if it is rejected or even if processing of it is merely postponed (*Pfizer Animal Health* v *Council*, paragraph 72 above, paragraphs 101 and 102, and *Alpharma* v *Council*, paragraph 72 above, paragraphs 93 and 94).

82 In the light of the foregoing, it must be found that the relevant rules in the present case do not lay down any procedural guarantees within the meaning of the case-law cited in paragraph 72 et seq. above, protecting the applicants and on which they may rely in order to show that the contested act produces binding legal effects with regard to them.

— The existence of procedural guarantees arising from general principles of law

83 In the context of their argument concerning the administrative and individual nature of the procedure in question, the applicants refer to the Commission's obligation diligently and impartially to examine all relevant evidence and legal submissions put forward by the operators concerned ('the duty of diligence'). According to the applicants the duty of diligence is a procedural guarantee protecting them in the context of the preliminary assessment of the intrinsic properties of the substances, and the Commission's compliance with that duty must be subject to review by the Community judicature.

84 It should be pointed out in that regard, first of all, that it is true that the participation of representatives of the industry concerned is an important factor in the permanent and effective adaptation of Directive 67/548 required by the rapid technical and scientific progress in that industry. That finds an echo in particular in the obligations to inform which weigh on the operators concerned (see paragraph 76 et seq. above) and in the composition of the working group which assists the Commission in that task and in which the representatives of the industry concerned take part. The interests of the economic operators are also appropriately represented in the context of the procedure for the adaptation of Directive 67/548 to technical progress (see, by analogy, the order in *Molkerei Großbraunshain and Bene Nahrungsmittel* v *Commission*, paragraph 73 above, paragraph 60). For the sake of completeness it may be said that the effectiveness of that representation is further apparent in the present case from the account taken by the working group of the information provided by the industry in question, as confirmed by the various documents in the file.

85 It is also certain that the Commission and the working group which are the recipients of that information are required, in the course of the preliminary assessment phase preceding the drafting of a proposal to amend Directive 67/548, to examine carefully and impartially all relevant evidence in the case in question (see by analogy *Pfizer Animal Health* v *Council*, paragraph 72 above, paragraphs 171 and 172, and *Alpharma* v *Council*, paragraph 72 above, paragraphs 182 and 183, which refers to the judgment in *Technische Universität München*, paragraph 43 above,

paragraph 14). It should further be noted that in the context of the Community rules governing antibiotics in animal feedingstuffs and the application of the precautionary principle which requires a scientific assessment of the risks as exhaustive as possible on the basis of scientific opinions based on the principles of excellence, transparency and independence, the Court has held that the duty of diligence is an important procedural safeguard in order to ensure that the measures are scientifically objective and to avoid the adoption of arbitrary measures (*Pfizer Animal Health* v *Council*, paragraph 172, and *Alpharma* v *Council*, paragraph 183).

86 However, contrary to what the applicants argue, it does not follow from that case-law or from that cited at paragraph 72 et seq. above that the operators concerned can rely on the duty of diligence in the context of a procedure resulting in the adoption of measures of general application in the same way as they may rely on procedural guarantees in the context of a procedure resulting in the adoption of an administrative act of individual application. On the contrary, the Court finds that in the context of the case-law referred to above, as in the present case, the duty of diligence is essentially an objective procedural guarantee arising from an absolute and unconditional obligation on the Community institution relating to the drafting of an act of general application and not the exercise of any individual right.

87 In the context of procedures resulting in the adoption of measures of general application such as that in the present case, the classification of the duty of diligence as a procedural guarantee does not imply that it confers rights directly on the operators taking part in the procedure in question and gives them access to the Community Courts. That interpretation is borne out by the fact that in *Pfizer Animal Health* v *Council* and *Alpharma* v *Council* (paragraph 72 above) the action for annulment was held to be admissible not on the basis of the duty of diligence as a procedural guarantee protecting the applicants but on the basis of other criteria, including procedural guarantees expressly laid down by the legislation in question, so that the applicants were considered to be individually concerned by the contested regulation (*Pfizer Animal Health* v *Council*, paragraph 72 above, paragraph 90 et

seq., and *Alpharma* v *Council*, paragraph 72 above, paragraph 82 et seq.). Furthermore, in those judgments, the duty of diligence was only taken into account in assessing the legality of the contested measures (*Pfizer Animal Health* v *Council*, paragraph 72 above, paragraph 171 et seq., and *Alpharma* v *Council*, paragraph 72 above, paragraph 182 et seq.).

88 In the context of the procedure for the adaptation of Directive 67/548 to technical progress, the duty of diligence is primarily an essential and objective procedural requirement, imposed in the public interest by legislation meeting the requirements of scientific objectivity and based on the principles of excellence, transparency and independence (see, by analogy, *Pfizer Animal Health* v *Council*, paragraph 72 above, paragraphs 171 and 172; and the Opinion of Advocate General Poiares Maduro in Case C-141/02 P *Commission* v *max.mobil* [2005] ECR I-1283, paragraphs 55 and 56). It follows that the scope of the duty of diligence is clearly distinguishable from that pertaining to the administrative procedures resulting in the adoption of individual measures in which the protective nature of the duty of diligence in relation to individuals has been recognised by the case-law (see, in particular, *Technische Universität München*, paragraph 43 above, paragraph 14; Case T-167/94 *Nölle* v *Council and Commission* [1995] ECR II-2589, paragraphs 73 to 76; and Case T-231/97 *New Europe Consulting and Brown* v *Commission* [1999] ECR II-2403, paragraph 37 et seq.). Incidentally, even if, in the context of a procedure resulting in the adoption of measures of general application, the duty of diligence does not engender any individual right for individuals to bring an action for annulment, that does not preclude them from pleading before the Community Courts an infringement of that obligation by a Community institution, provided that the conditions for the admissibility of an action for annulment or an action for damages are met (see, to that effect, Case T-285/03 *Agraz and Others* v *Commission* [2005] ECR II-1063, paragraphs 49 to 54).

89 It should be noted in that connection that according to the case-law cited at paragraphs 73 and 74 above, in the context of drafting acts of general application the general principles of Community law, such as the right to be heard and likewise the duty of diligence, do not have the same scope as they do in administrative procedures for the adoption of an act of individual application. It follows that the protective principles developed in the case-law in relation to such administrative procedures cannot be applied as such to procedures resulting in the adoption of

measures of general application and that, consequently, in the latter case, the existence of a duty of diligence cannot imply the grant of an individual procedural guarantee (see, to that effect, on the right to a hearing, *Pfizer Animal Health* v *Council*, paragraph 72 above, paragraph 487 and the case-law cited). It also follows that the applicants err in relying on the judgment in *max.mobil* v *Commission* (paragraph 43 above), which has in any case now been set aside by the Court on appeal (*Commission* v *max.mobil*, paragraph 89 above).

90 It follows from the foregoing that the applicants' argument relating to the duty of diligence must be rejected.

91 Consequently, given the absence of express or implied procedural guarantees protecting the applicants in the context of the procedure for the adaptation of Directive 67/548 to technical progress, the contested act cannot be regarded as producing binding legal effects with regard to them and therefore as an act open to review under Article 230 EC.

92 In the light of the foregoing, it must be found that the contested act does not produce binding legal effects with regard to the applicants and therefore is not such as to change their legal situation. It is not therefore an act open to review within the meaning of the fourth paragraph of Article 230 EC.

The applicants' right to an effective legal remedy

93 It is necessary lastly to examine the applicants' argument that the admissibility of their action arises from the principle of legality and from the right to an effective legal remedy, since the Court is the only jurisdiction empowered to rule on the legality of the contested act.

94 It suffices to refer in this connection to the case-law according to which any lack of a legal remedy, even if established, cannot warrant modifying by way of judicial interpretation the system of legal remedies and procedures laid down by the Treaty. In no event, according to that case-law, can it enable an action for annulment brought by a natural or legal person to be declared admissible where it does not satisfy the conditions laid down in the fourth paragraph of Article 230 EC (Case C-263/02 P *Commission* v *Jégo-Quéré* [2004] ECR I-3425, paragraph 36; Case T-138/98 *ACAV and Others* v *Council* [2000] ECR II-341, paragraph 68; and the order in *Bactria* v *Commission*, paragraph 72 above, paragraph 54).

95 It should be further noted that the applicants have not shown that an economic operator in their situation is not able to challenge the validity of the failure to declassify rosin by an action brought before the national courts against national implementing measures adopted by the Member State concerned. Such proceedings could give rise to a reference for a preliminary ruling as to the validity of the directive concerned under Article 234 EC (see, to that effect, the order of 30 April 2003 in Case T-154/02 *Villiger Söhne* v *Council* [2003] ECR II-1921, paragraphs 60 and 61). It appears to be possible that the applicants may, at the very least, seek the adoption of a national measure reviewable by a national court by, for example, applying to the national authorities for a derogation from the application of Directive 67/548 in respect of rosin and of any national legislation implementing it. Furthermore, it should be noted that the applicants have, to this day, not even sought to challenge by any legal means the current classification of rosin as a sensitising substance, whereas that classification has already been in force for more than 10 years, having arisen as a result of the amendments introduced by Directives 93/72 and 94/69. They do not therefore demonstrate the absence of appropriate national remedies. It should be added that according to the case-law of the Court of Justice, even if it can be shown, following a detailed examination of national procedural rules, that those rules do not allow the individual to bring proceedings to challenge the validity of the contested act, that in no way undermines the preceding considerations, given that such a system would require the Court in each particular case to examine and interpret national procedural law, thus exceeding the bounds of its jurisdiction when reviewing the legality of Community measures (Case C-50/00 P *Unión de Pequeños Agricultores* v *Council* [2002] ECR I-6677, paragraph 43).

96 Accordingly, the application for annulment of the contested measure must be rejected as inadmissible.

2. *The admissibility of the claim for compensation*

Arguments of the parties

97 The defendant submits that the claim for compensation is also inadmissible because it is time-barred. In the alternative, it submits that it is manifestly unfounded.

98 The intervener lodged no observations as to the admissibility of the claim for compensation.

99 The applicants point out that for an action for damages to be admissible, it is necessary to prove the illegality of the defendant's conduct, the damage incurred and the existence of a causal link between the conduct and the damage (Case 5/71 *Zuckerfabrik Schöppenstedt* v *Council* [1971] ECR 975).

100 As regards, first, the illegality of the conduct, it is clear in the present case from the various grounds of annulment that the defendant's conduct upon the adoption of the contested act, including the conduct of its officials in the phase prior to its adoption

was illegal. The applicants submit in particular that by refusing to declassify rosin, although that was 'scientifically justified', the Commission not only exceeded its powers but also failed to examine their complaint and request carefully and impartially, thereby infringing the duty of sound administration.

101 According to settled case-law, unlawful conduct suffices to establish non-contractual liability on the part of the Community where the contested act is not legislative in nature and where the Commission does not have a wide discretion. In this case, the contested act is an individual measure addressed to the applicants and not a legislative act. Even if the contested act were legislative in nature — quod non — its adoption by the Commission is, according to the applicants, a sufficiently serious breach of a superior rule of law for the protection of individuals (*Zuckerfabrik Schöppenstedt* v *Council*, paragraph 99 above, and Case T-390/94 *Schröder and Others* v *Commission* [1997] ECR II-501) by reason of the breach of the Treaty and of various fundamental principles of Community law for the protection of the rights of individuals and of their legitimate expectations. The applicants further submit that the Commission does not enjoy a wide discretion in making decisions as to the inclusion of a substance in Annex I to Directive 67/548, because it is bound by the rules and criteria laid down by that directive, to classify substances in accordance with their intrinsic properties.

102 Second, with respect to the damage caused by the adoption of the contested act, the applicants submit that as a result of its unlawful classification the applicants' customers in the European Union have lost confidence in rosin, are exploring alternative materials, and in certain instances are phasing out their use of products containing rosin, thereby reducing the relevant market and their profits. Furthermore, the applicants have spent much time, energy and money during the classification and labelling process in the past 10 years, with in particular recourse to expert legal and technical advice in preparing the present action. The applicants consider that their financial loss as a result to date exceeds EUR 250 000. In the

alternative, the applicants ask the Court to declare the Community liable for imminent damage foreseeable with sufficient certainty, even if the damage cannot yet be precisely assessed (Joined Cases 56/74 to 60/74 *Kampffmeyer and Others* v *Commission and Council* [1976] ECR 711, paragraph 6).

103 Third, as regards the causal link between the illegality of the contested act and the damage suffered, the applicants submit that the cessation of their commercial relations with their clients and the substitution by such customers of other products for rosin arises directly from the contested act. The applicants ask the Court in that regard to declare that the defendant is obliged to compensate the damage suffered as a result of the adoption of the contested act and to order that the amount of the damages be agreed between the parties or fixed by the Court in the absence of such agreement (Case 74/74 *CNTA* v *Commission* [1975] ECR 533).

104 As regards the defendant's objection that the claim for compensation is time-barred, the applicants submit that the date of adoption of the contested act is the starting point for bringing such a claim because it closes the administrative assessment procedure for rosin. Accordingly, the Commission would probably have rejected any action filed before the adoption of the contested act as premature. The contested act is dated 23 August 2003 and the applicants brought the action on 29 October 2003, that is, within the five-year time-limit prescribed for bringing an action for damages under the second paragraph of Article 288 EC.

Findings of the Court

105 The defendant submits that the claim for compensation is time-barred because brought out of time, namely more than 10 years after the classification of rosin as a

dangerous substance by Directives 93/72 and 94/69. In the alternative, the defendant submits that that claim is manifestly unfounded, referring to the order of 17 December 2003 in Case T-346/03 *Krikorian and Others* v *Parliament and Others* [2003] ECR II-6037, paragraphs 14 and 15).

106 It should, first of all, be noted that according to Article 46 of the Statute of the Court of Justice actions against the Community for non-contractual liability have a time-limit of five years from the date of the facts giving rise to the action. The limitation period thus laid down cannot begin to run before all the requirements governing the obligation to make good the damage are satisfied. Those requirements are the existence of unlawful conduct on the part of the Community institutions, of the damage alleged and of a causal link between that conduct and the loss claimed (Joined Cases 256/80, 257/80, 265/80, 267/80 and 5/81 *Birra Wührer and Others* v *Council and Commission* [1982] ECR 85, paragraph 10; Case T-20/94 *Hartmann* v *Council and Commission* [1997] ECR II-595, paragraph 107; and Case T-76/94 *Jansma* v *Council and Commission* [2001] ECR II-243, paragraph 76). The requirement as to the existence of specific damage is satisfied if the damage is imminent and foreseeable with sufficient certainty, even if it cannot yet be precisely assessed (Case 281/84 *Zuckerfabrik Bedburg and Others* v *Council and Commission* [1987] ECR 49, paragraph 14).

107 Where the Community's liability stems from a measure of general application, the limitation period cannot begin to run before the injurious effects of the measure have been produced and, consequently, before the persons concerned have suffered damage (*Birra Wührer and Others* v *Council and Commission*, paragraph 106 above, paragraph 10; Case T-246/93 *Bühring* v *Council* [1998] ECR II-171, paragraph 66; and the order of 17 January 2001 in Case T-124/99 *Autosalone Ispra dei Fratelli Rossi* v *EAEC* [2001] ECR II-53, paragraph 23).

108 In the present case, the defendant rightly observes that the classification of rosin as a dangerous substance, still in force, results ultimately from the amendment to Directive 67/548 by Directive 94/69 which came into force on 3 January 1995, the

deadline for its implementation into national law by the Member States being 1 September 1996. It is thus clear that the contested act did not change in any way the classification already in force.

109 It follows that the damage suffered by the applicants, even if proven, can in no circumstances have arisen from the contested act, but results from the implementation of Directive 67/548 and at the very most from the amendment thereto regarding the classification of rosin. Furthermore, as the defendant rightly submits, it is clear from paragraph 99 of the application that the applicants themselves essentially consider that the source of the alleged damage is 'the unlawful classification', that is to say the measure classifying rosin as a dangerous substance. Therefore, the applicants' allegation that the contested act is 'the starting point for such damages as it closes the administrative assessment of rosin ...' must be rejected. Lastly, given the Court's findings in paragraph 58 et seq. above, that assertion is in any event unfounded.

110 Accordingly, it is necessary to determine the point in time when the requirements for liability for damages might have been met in the present case.

111 The Court finds in that regard that even after the defendant expressly pleaded the limitation period, the applicants were not able to adduce specific evidence to prove the date on which or the period during which all the requirements for liability to compensate for the alleged damage were met. They merely submitted in vague and unsubstantiated terms that following the 'unlawful classification', their European customers lost confidence in rosin, sought alternative products and, in certain cases, phased out their use of products containing rosin, thereby reducing the applicants' market shares and profits. Similarly, the applicants have not specified the immediate or continuing nature of the damage allegedly suffered. Therefore, regardless of

whether those factors are, in themselves, sufficient to prove the existence of damage and of a causal link with the allegedly unlawful conduct, neither the precise date on which nor even the period during which such a harmful situation was created by the classification in question can be inferred from those allegations.

112 In the light of the foregoing, the Court considers that the defendant was right to submit that the origin of the alleged damage, assuming that it was in fact caused by the classification of rosin, and therefore the satisfaction of the requirements laid down in the second paragraph of Article 288 EC, must necessarily lie either immediately after the entry into force of Directive 94/69, or at the latest immediately after the implementation of Directive 94/69 in the Member States, for which the deadline was set at 1 September 1996. Given the applicants' own affirmations, according to which the classification of rosin as a dangerous substance gave rise to the alleged damage, it is highly unlikely that that classification produced or even began to produce its allegedly harmful effects only at the end of the 1990s or later.

113 In any event, given the defendant's detailed challenge in paragraphs 51 and 53 of its plea of inadmissibility on that point, it was for the applicants, who make only very vague assertions in their application, to adduce further evidence as to the date or the exact period of the onset of the allegedly harmful effects and the potentially continuing nature of the alleged damage. That is especially the case in view of the fact that, on their own admission, the applicants knew from the 1990s, when they began to make concerted efforts to obtain its declassification by the relevant Community authorities, of the harmful effects on their business of the classification of rosin.

114 In the absence of a detailed reply to this point from the applicants in their reply to the plea of inadmissibility the Court in ruling on that plea, at least, must confine

itself to the deadline laid down for the implementation of Directive 94/69 in national law, the date on which the classification of rosin still in force undeniably produced effects in the legal orders of the Member States.

115 It follows that under Article 46 of the Statute of the Court of Justice, the limitation period of five years for bringing a claim for compensation began to run at the latest on 1 September 1996 if the damage alleged by the applicants is an immediate damage. In that case, in the absence of an intervening act causing time to stop running for the purposes of the limitation period before the application was lodged on 29 October 2003, the applicants' action for non-contractual liability on the part of the Community is time-barred, so that the claim for compensation is inadmissible.

116 Although the applicants have not submitted specific arguments in that connection, the Court finds that the damage they allege is not necessarily immediate but that it is likely to be continuing. In such a case of continuing damage, the limitation period referred to in Article 46 of the Statute of the Court applies, by reference to the date of the event which interrupted the limitation period, to the period preceding that date by more than five years and does not affect rights which arose during subsequent periods (Case T-28/03 *Holcim (Deutschland)* v *Commission* [2005] ECR II-1357, paragraph 70 and the case-law cited). In that regard, Article 46 of the Statute of the Court treats as an intervening event either the institution of proceedings before the Court or the making of a prior application by the aggrieved party to the relevant institution.

117 However, it is clear from the file that the applicants did not, as the second sentence of Article 46 of the Statute of the Court requires, make an application to the Commission for relief prior to bringing proceedings. Accordingly, only the application lodged in the present case on 29 October 2003 may conceivably be regarded as an intervening act for the purposes of the limitation period within the meaning of Article 46 of the Statute of the Court.

118 In the light of the foregoing, the present claim, on the basis of continuing damage, must in any event be rejected as inadmissible in so far as it concerns the damage allegedly suffered in the period more than five years before that date, that is to say prior to 29 October 1998.

119 Moreover, to the extent that the claim for compensation is not time-barred in respect of any continuing damage, the Court, which under Article 113 of the Rules of Procedure may at any time of its own motion consider whether there is any absolute bar to proceeding with an action, finds that the claim for compensation is also inadmissible owing to the failure to comply with the requirements laid down in Article 44(1)(c) of those Rules.

120 Under that provision, any application must state the subject-matter of the proceedings and a summary of the pleas in law on which the application is based. That statement must be sufficiently clear and precise to enable the defendant to prepare its defence and for the Court to give judgment on the action without recourse to further information. In order to guarantee legal certainty and sound administration of justice it is necessary, in order for an action to be admissible, that the basic legal and factual particulars relied on be indicated, at least in summary form, coherently and intelligibly in the application itself. More particularly, an application seeking compensation for damage allegedly caused by a Community institution must set out the evidence from which the conduct which the applicant alleges against the institution can be identified, the reasons for which the applicant considers that there is a causal link between the conduct and the damage it claims to have suffered and the nature and extent of that damage (Joined Cases T-215/01, T-220/01 and T-221/01 *Calberson GE* v *Commission* [2004] ECR II-587, paragraph 176; Case T-19/01 *Chiquita Brands and Others* v *Commission* [2005] ECR II-315, paragraph 64 et seq.).

121 The Court finds that the application in the present case does not satisfy those requirements in that it does not clearly, unequivocally, coherently and fully set out

the evidence for the alleged damage on the one hand and the causal link between the allegedly unlawful conduct and that damage on the other.

122 The applicants' allegations as to the origin of the damage caused are so vague that the Court is not in a position to make a ruling. As is clear from the findings set out in paragraphs 108 to 113 above, it is impossible to identify with sufficient certainty the fact giving rise to the damage, or the start and therefore the duration of the alleged damage. Moreover, the applicants have failed to adduce sufficient evidence to show how the pecuniary loss estimated at at least EUR 250 000, which they claim to have suffered as a result of their concerted efforts to have rosin declassified, and the alleged damage resulting from the alleged loss of business with their customers, was caused by the unlawful conduct principally alleged, namely the contested act itself.

123 It should also be noted that the applicant's argument as to the causal link is contradictory: first, and principally, they allege that the damage results from the contested act itself, and secondly, contrary to the first allegation, they claim at least implicitly that it is the 'unlawful classification' which gave rise to their damage. Nevertheless, the applicants conclude at paragraph 102 of the application that 'with respect to the causal link between the illegality of the contested measure and the damages incurred ... it is clear that interruption of their commercial relationships with their customers, including the replacement by such customers of rosin with other substances, arises directly from the Commission's negative decision related to the delisting of rosin in Annex I to Directive 67/548'.

124 It follows that, as regards the identification of the alleged damage and the causal link between the allegedly unlawful conduct and that damage, the application does not satisfy the requirements laid down by Article 44(1)(c) of the Rules of Procedure. Lastly, even if the claim for compensation were admissible, it follows from all the foregoing that, in any event, it is manifestly unfounded.

125 The present claim for compensation must therefore be rejected as inadmissible.

3. *The admissibility of the plea of illegality raised under Article 241 EC*

Arguments of the parties

126 The defendant also challenges the admissibility of the plea of illegality raised by the applicants against Directives 93/72 and 94/69.

127 The intervener makes no observations as regards the admissibility of the plea of illegality.

128 The applicants claim in the alternative that, in the event that the claim for annulment is found to be inadmissible, the Court should declare that the inclusion of rosin in Annex I to Directive 67/548 is inapplicable to them, pursuant to Article 241 EC.

Findings of the Court

129 As regards the admissibility of the plea of illegality, it suffices to refer to the settled case-law to the effect that the possibility afforded by Article 241 EC of pleading the inapplicability of a measure of general application forming the legal basis of the contested decision does not constitute an independent right of action and recourse

may be had to it only as an incidental plea. Consequently, Article 241 EC cannot be invoked in the absence of an independent right of action given, in this case, the inadmissibility of the claims for annulment and for damages (Case 33/80 *Albini* v *Council and Commission* [1981] ECR 2141, paragraph 17; Joined Cases 87/77, 130/77, 22/83, 9/84 and 10/84 *Salerno and Others* v *Commission and Council* [1985] ECR 2523, paragraph 36; Case T-154/94 *CSF and CSME* v *Commission* [1996] ECR II-1377, paragraph 16; and the order of 19 September 2001 in Joined Cases T-54/00 and T-73/00 *Federación de Cofradías de Pescadores de Guipúzcoa and Others* v *Council* [2001] ECR II-2691, paragraph 82).

130 It follows that the plea of illegality raised under Article 241 EC must be rejected as inadmissible without its being necessary to consider whether the contested act is linked to Directives 93/72 and 94/69.

Costs

131 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been asked for in the other party's pleadings. Since the applicants have been unsuccessful they must, having regard to the form of order sought by the Commission, be ordered to pay the costs.

132 Under the first subparagraph of Article 87(4) of the Rules of Procedure, the Member States which have intervened in the proceedings are to bear their own costs. Accordingly, the Republic of Finland as intervener shall bear its own costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Third Chamber)

hereby orders:

1. **The action is dismissed as inadmissible.**

2. **The applicants shall bear their own costs and pay those incurred by the defendant.**

3. **The intervener shall bear its own costs.**

Luxembourg, 14 December 2005.

E. Coulon — Registrar

M. Jaeger — President

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