OPINION OF ADVOCATE GENERAL FENNELLY

delivered on 27 January 2000 *

1. This appeal against the judgment of the Court of First Instance in *Bergaderm and Goupil* v *Commission* [1] is notable principally for raising the question whether a directive may be deemed to be administrative rather than legislative in character for the purpose of determining the applicable standard of unlawfulness of the adopting institution's conduct in an action for damages for non-contractual liability.

I — Relevant law

2. The third recital in the preamble to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products [2] (hereinafter 'the Cosmetics Directive'), as amended in particular by Council Directive 93/35/EEC of 14 June 1993, [3] states that the pursuit of the objective of safeguarding public health must inspire Community legislation in the cosmetics sector. The ninth recital states that technical progress necessitates rapid adaptation of the technical provisions defined in that directive and in subsequent directives in the field.

3. Article 4 of the Cosmetics Directive requires the Member States to prohibit the marketing, beyond the limits and outside the conditions laid down therein, of cosmetic products containing any of the substances specified in, *inter alia*, the 'List of substances which cosmetic products must not contain' set out in Annex II to that directive.

4. Article 9 of the Cosmetics Directive establishes a Committee on the adaptation to technical progress of the directives on the removal of technical barriers to trade in the cosmetic products sector (hereinafter 'the Adaptation Committee'), composed of representatives of the Member States and chaired by a representative of the Commission.

5. Commission Decision 78/45/EEC of 19 December 1977 [4] established a Scientific

* Original language: English.

1 — Case T-199/96 [1998] ECR II-2805, hereinafter 'the contested judgment'.

2 — OJ 1976 L 262, p. 169.

3 — OJ 1993 L 151, p. 32.

4 — OJ 1978 L 13, p. 24.

Committee on Cosmetology (hereinafter 'the Scientific Committee') attached to the Commission. Under Article 2 of that decision, the Committee's task is to give the Commission an opinion on any problem of a scientific or technical nature in the field of cosmetic products and particularly on substances used in the preparation of cosmetic products and on the conditions of use of these products. The members of the Scientific Committee are to be appointed by the Commission from among 'highly qualified leading scientific figures with competence in the field [of cosmetic products]' (Article 4); the representatives of the Commission departments concerned are to attend the meetings of the Committee (Article 8(2)); the Commission may also invite 'leading figures with special qualifications in the subjects under study' to attend those meetings (Article 8(3)); and the Scientific Committee may also form working parties which are to meet when convened by the Commission (Articles 7 and 8).

6. Article 8(2) of the Cosmetics Directive provides that the amendments necessary for adapting Annex II to technical progress are to be adopted in accordance with the procedure laid down in Article 10. Article 10(2) provides that the representative of the Commission shall submit to the Adaptation Committee a draft of the measures to be adopted. The Committee is required to deliver its opinion on the draft within a time-limit set by the chairman according to the urgency of the matter. Article 10(3) provides as follows:

'(a) The Commission shall adopt the proposed measures when they are in accordance with the opinion of the Committee.

(b) Where the proposed measures are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by qualified majority.

(c) If, within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.'

7. After a series of studies and consultations which commenced in 1987, which are briefly outlined below, the Eighteenth Commission Directive 95/34/EC of 10 July 1995 adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products [5] (hereinafter 'the contested Directive') inserted the following

5 — OJ 1995 L 167, p. 19.

text as reference number 358 in Annex II to the Cosmetics Directive:

'Furocoumarines (e.g. trioxysalan, 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used.

In sun protection and bronzing products, furocoumarines shall be below 1 mg/kg.'

Article 2 of the contested Directive requires the Member States to take all the necessary measures to ensure that, as from 1 July 1996, neither manufacturers nor importers established in the Community place on the market products which do not comply with that directive and that, as from 1 July 1997, such products can no longer be sold or otherwise supplied to the final consumer.

II — Facts

8. The first appellant, Laboratoires Pharmaceutiques Bergaderm (hereinafter 'Bergaderm'), is a company whose activities at the relevant time consisted of the manufacture, purchase and sale of sun creams and oils, eaux de toilette and perfumes. The second appellant, Jean-Jacques Goupil, was its chief executive. Bergaderm was formally put into liquidation on 10 October 1995, pursuant to a procedure initiated on 6 July 1995.

9. One of Bergaderm's products was Bergasol, a sun oil containing, in addition to vegetable oil and filters, bergamot essence. Some of the molecules to be found in bergamot essence are 'psoralens', otherwise known as 'furocoumarines'. One of these is 'bergapten', scientifically called 5-methoxypsoralen (hereinafter '5-MOP'). 5-MOP strongly induces photodynamism, with the result that the presence of bergamot essence in Bergasol greatly accelerates the tanning process. [6] However, 5-MOP, in its chemically pure state, is suspected of being carcinogenic. Different studies have been carried out to determine whether the 5-MOP present in the bergamot essence used in a tanning product is also carcinogenic. These studies have produced widely differing conclusions. [7]

10. In March 1987, Germany asked the Commission to consider the possibility of restricting the maximum level of naturally occurring psoralens in sun oil. The Commission sought the opinion of the Scientific Committee. The study carried out by one of the Scientific Committee's members con-

6 — See further paragraph 8 of the contested judgment.

7 — See paragraphs 11 and 12 of the contested judgment.

cluded that, in the presence of ultraviolet rays, 5-MOP is highly phototoxic and photomutagenic, hence potentially carcinogenic. [8] Despite some disagreement among its members, the Scientific Committee recommended on 2 October 1990 that the maximum level of 5-MOP in sun oils should be set at 1 mg/kg.

11. The appellants organised a seminar in June 1991 on the effects of psoralens which culminated in a number of scientists signing a document stating that the risk of photomutagenic and photocarcinogenic effects was negligible where 5-MOP was combined with other sun filters. Subsequently, the Scientific Committee invited a number of outside experts to a meeting on 24 September 1991 to discuss the results of this seminar. After describing their research on sun oils with bergamot essence containing 15 to 50 mg/kg of 5-MOP, a number of scientists suggested that sun products containing sunscreens and 5-MOP were no less safe than other such products, or were possibly safer. [9] None the less, the Scientific Committee confirmed its earlier recommendation on 4 November 1991.

12. The Adaptation Committee first discussed psoralens as ingredients in sun oils on 17 December 1991, without reaching any conclusions. At a further meeting on 1 June 1992, at which the Commission asked it to take a position on restricting psoralens in sun products to either 60 mg/kg or 1 mg/kg, half the members of the Scientific Committee voted for the former figure and half for the latter. On 2 June 1991, the Scientific Committee confirmed its opinion of 4 November 1991 (proposing the restriction to 1 mg/kg), as it did again on 24 June 1994 despite continuing controversy in scientific circles. [10]

13. At a meeting on 16 February 1995, the working party on 'cosmetic products', which was composed of all the members of both the Scientific Committee and the Adaptation Committee, voted, with the sole exception of the French representative, to endorse a maximum level of psoralens of 1 mg/kg in sun products. On 28 April 1995, the Adaptation Committee recommended that the level of psoralens in such products should not exceed 1 mg/kg. All the delegations within the Committee voted in favour of that opinion save for the French delegation. The Finnish delegation was absent. The Commission adopted the contested Directive on 10 July 1995.

14. During the administrative procedure which led to the adoption of the contested Directive, the appellants regularly submitted observations on their own initiative, sending the Commission and members of

8 — See the reference to Mr Fielder's study at paragraph 12 of the contested judgment.

9 — See paragraphs 16 to 18 of the contested judgment.

10 — See paragraph 22 of the contested judgment.

the Scientific Committee letters and documents containing data and scientific evaluations on Bergasol. On 5 November 1990, moreover, Mr Goupil addressed the working party on 'cosmetic products'. That working party met to discuss Bergasol on a number of occasions between 1990 and 1995, at times on the basis of written or oral observations submitted by Bergaderm.

III — Proceedings before the Court of First Instance

15. On 4 December 1996, the appellants applied to the Court of First Instance pursuant to Articles 178 and 215, second indent, of the EC Treaty (now Article 235 EC and Article 288 EC, second indent) for an order that the Commission pay damages of FRF 152 867 090 to Bergaderm and of FRF 161 309 995.33 to Jean-Jacques Goupil and pay the costs of the proceedings.

16. The appellants submitted before the Court of First Instance that the contested Directive was in reality an administrative act, as it exclusively concerned the product Bergasol. They alleged that the Commission had committed two procedural errors. First, it had failed to submit its proposal to impose a maximum level of psoralens in sun products to the Council when, as the appellants allege, the Adaptation Committee delivered an unfavourable opinion on 1 June 1992. Secondly, the Commission had shown no regard for the rights of the defence, by failing to pass on to the Adaptation Committee scientific information which the appellants had submitted to the Scientific Committee. Furthermore, the procedure before the Adaptation Committee had not been *inter partes*. The appellants also contended that the Commission had committed a manifest error of assessment, leading to a breach of the principle of proportionality, by failing to distinguish between the possible health risks posed by 5-MOP as a chemical substance in its pure state and those posed by the use in a sun product of 5-MOP occurring in natural essences.

IV — The contested judgment

17. The Court of First Instance analysed the conditions governing Community liability as follows:

'48 Under the second paragraph of Article 215 of the Treaty and the general principles to which that provision refers, Community liability depends on fulfilment of a set of conditions regarding the unlawfulness of the conduct alleged against the institution concerned, the fact of damage and the existence of a causal link between the conduct in question and the damage complained of (Case C-257/90 *Italsolar* v *Commission* [1993] ECR I-9, paragraph 33, and Case T-336/94 *Efi-*

sol v *Commission* [1996] ECR II-1343, paragraph 30). As regards liability arising from legislative measures, the conduct with which the Community is charged must constitute a breach of a higher-ranking rule of law for the protection of individuals (Joined Cases T-195/94 and T-202/94 *Quiller and Heusmann* v *Council and Commission* [1997] ECR II-2247, paragraph 49).

49 In the present proceedings, compensation is sought for damage related to the Commission's conduct in connection with the preparation and adoption of a directive amending the cosmetics directive.

50 The application is manifestly concerned with legislative measures. The directive is a Community measure of general application, and the fact that the number or even the identity of the persons to whom such a measure applies can be determined is not such as to call in question its legislative character (order of the Court of Justice of 23 November 1995 in Case C-10/95 P *Asocarne* v *Council* [1995] ECR I-4149, paragraph 30). Directive 95/34 concerns, in a general and abstract manner, all the traders in the Member States who, on expiry of the time-limits set for its transposition into the various national legal systems, are operating in the sector in question.

51 It is necessary therefore to determine whether or not the Commission disregarded a higher-ranking rule of law for the protection of individuals.'

18. The Court of First Instance rejected the argument that the Commission's proposal should have been submitted to the Council after the meeting of the Adaptation Committee of 1 June 1992. It did not decide whether or not Article 10 of the Cosmetics Directive contains superior rules of law for the protection of individuals. It stated that it was clear from the minutes of that meeting that, as the Member State delegations were evenly divided between the two options presented to them, the Commission decided to withdraw its proposal. This situation was not covered by Article 10(3)(a) or (b) of the Cosmetics Directive, as the 'proposed measures' no longer existed. The Court of First Instance stated in this regard that the Commission must have enough time to arrange a fresh examination of the relevant scientific issues. [11]

19. With regard to the principle that the procedure should be *inter partes*, the Court of First Instance observed [12] that this was a fundamental principle applicable in all *administrative* proceedings initiated against a person which were liable to culminate in

11 — The Court of First Instance cited Case T-105/96 *Pharos* v *Commission* [1998] ECR II-285, paragraphs 65 and 68. See generally paragraphs 52 to 56 of the contested judgment.

12 — See generally paragraphs 58 to 60 of the contested judgment.

a measure adversely affecting that person, [13] but that it did not apply in the context of the *legislative* process [14] except in exceptional cases expressly provided for. [15] No such provision was made in the Cosmetics Directive. In any event, it was clear from the facts that the appellants had ample opportunity to express their views to the Scientific Committee and the Commission and that they were allowed to address the ad hoc group of experts.

20. The Court of First Instance also rejected the plea of manifest error of assessment and breach of the principle of proportionality. [16] It observed that the Commission had evaluated the effects of 5-MOP in combination with sun-product ingredients such as solar filters. There was nothing to suggest that the Commission had misunderstood the scientific arguments before it. As the Commission was not in a position to carry out itself the scientific assessments necessary to pursue the Cosmetics Directive's objective of public-health protection, the Scientific Committee had the task of assisting it in this respect. [17] Thus, the Commission could not be criticised for relying upon that body's opinion. Furthermore, in cases of uncertainty regarding risks to consumers' health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks have become fully apparent. [18]

V — The appeal

21. The appellants lodged their appeal on 24 September 1998, requesting the Court to annul the contested judgment and to make the order awarding damages and costs initially sought before the Court of First Instance. The French Republic has intervened in support of the Commission. The appellants rely on three grounds. The Commission contests the admissibility of each of these, on the basis that they merely reiterate arguments already presented before the Court of First Instance.

22. The first ground of appeal is that the Court of First Instance erred in law in categorising the contested Directive as a normative act rather than as an administrative act. Despite its form, it individualised the appellants relative to all other persons because Bergaderm was the only undertaking producing and marketing sun oil containing 5-MOP and Mr Goupil held the only patent for incorporating natural citrus essences containing 5-MOP in a sun product. By virtue of this patent, he had

13 — Case T-450/93 *Lisrestal and Others* v *Commission* [1994] ECR II-1177, paragraph 42.

14 — Case T-521/93 *Atlanta and Others* v *European Community* [1996] ECR II-1707, paragraph 70.

15 — In particular, Council Regulation (EC) No 384/96 of 22 December 1995 on protection against dumped imports from countries not members of the European Community, OJ 1996 L 56, p. 1.

16 — See paragraphs 62 to 67 of the contested judgment.

17 — The Court of First Instance cited Case C-212/91 *Angelopharm* v *Hamburg* [1994] ECR I-171, paragraphs 32, 34 and 38.

18 — Paragraph 66 of the contested judgment. Case C-157/96 *R* v *MAFF and Others, ex parte National Farmers' Union and Others* [1998] ECR I-2211 (hereinafter '*National Farmers' Union*'), paragraph 63, is cited.

obliged rival producers to abandon production of sun oil containing 5-MOP. It is also material that the titles of certain reports of the Scientific Committee refer expressly to Bergasol. The Commission replies that the contested Directive only affects the appellants because of their involvement in a commercial activity open to all undertakings. They had not proved the existence of the relevant patents and the prohibition of other undertakings from making or marketing sun creams containing 5-MOP. Furthermore, a patent was of limited duration and could be made the subject of compulsory licensing. In any event, the Community institutions could not be prevented from responding by way of legislation to the health risks posed by a product simply because patents had been granted in respect of that product.

23. The appellants' second ground is that the Court of First Instance committed a manifest error of appreciation regarding the scientific question, as all the scientific evidence suggested that Bergasol was harmless and provided effective protection against the sun. In addition, they contest the applicability of the precautionary principle. The Commission responds that this ground contests the findings of fact of the Court of First Instance and is, therefore, inadmissible. In any event, the appellants failed to show that Bergasol was risk-free and that the Commission was wrong to accept the recommendation of the Scientific Committee.

24. Thirdly, the appellants consider that the Court of First Instance failed to acknowledge three breaches by the Commission of superior rules of law for the protection of individuals. The Court of First Instance should have condemned as such a breach the Commission's failure to submit its proposal to the Council, as the Adaptation Committee had adopted a negative opinion on 1 June 1992. In addition, it failed to condemn a flagrant breach of the rights of the defence. This was compounded by the participation in the Adaptation Committee of Austrian and Swedish representatives, although they had not been involved in earlier discussions before the 1995 enlargement of the Community. Finally, the Commission had breached the principles of proportionality and of legitimate expectations by excluding Bergasol from the market without any public-health justification. This was all the more serious because the Commission had failed to take into account the interests of a distinct group of economic operators. [19]

VI — Analysis

A — *Admissibility*

25. The Commission contests the admissibility of all three grounds of appeal on the

19 — Joined Cases C-104/89 and C-37/90 *Mulder* v *Council and Commission* [1992] ECR I-3061, paragraphs 16 and 17.

basis that the appellants have merely reiterated arguments already submitted to the Court of First Instance. I have already criticised, in my Opinion in *Carbajo Ferrero* v *Parliament*,[20] over-liberal recourse to this argument. As in that case, the appeal in the present case identifies, in respect of each ground of appeal, those elements of the contested judgment with which the appellants take issue, and outlines — sometimes at length, sometimes rather laconically — their reasons for doing so.[21] That this is sufficient to satisfy the requirements of admissibility emerges clearly from the judgment in *Carbajo Ferrero* v *Parliament*, in which the Court held the main ground of appeal to be admissible.[22]

B — *The first ground of appeal*

26. The appellants claim that the Court of First Instance, in determining which standard to apply when assessing the Commission's conduct, erred in law by classifying the contested Directive as a legislative measure rather than as an administrative act. Breach of a superior rule of law for the protection of individuals is a condition of a successful claim for damages flowing from a legislative measure. On the other hand, any kind of illegality may give rise to liability to pay compensation for damage caused by an administrative act.

27. A directive is normally, from its very nature and method of adoption and transposition, a measure having general scope.[23] The Court will, none the less, examine, if necessary, whether or not a directive is general in nature in all respects,[24] or is, at least in part, of individual concern to an applicant for its annulment[25] (as distinct from an applicant for damages flowing from it). It has, thus, at the very least, left open the question whether or not such individual concern may be possible in certain circumstances in the case of a directive, giving rise to standing on the part of the affected person to challenge its

20 — Case C-304/97 P [1999] ECR I-1749, paragraph 8 of my Opinion.

21 — The sole exceptions are the argument of proportionality presented as part of the third ground of appeal, which is substantially identical to the second ground of appeal, and a new argument of breach of the principle of legitimate expectations which was also submitted as part of the third ground of appeal. I recommend below that the latter argument be rejected as inadmissible pursuant to Article 113(2) of the Rules of Procedure of the Court of Justice.

22 — Ibid., paragraphs 25 to 28.

23 — Case 70/83 *Kloppenburg* v *Finanzamt Leer* [1984] ECR 1075, paragraph 11; Case 160/88 R *Fédération Européenne de la Santé Animale and Others* v *Council* [1988] ECR 4121 (hereinafter '*Fedesa*'), paragraph 28; Case C-298/89 *Gibraltar* v *Council* [1993] ECR I-3605 (hereinafter '*Gibraltar*'), paragraph 16.

24 — *Fedesa*, paragraph 28; *Gibraltar*, paragraphs 19 to 23.

25 — Case 138/88 *Flourez and Others* v *Council* [1988] ECR 6393 (hereinafter '*Flourez*'), paragraphs 10 to 12; *Asocarne* v *Council*, op. cit. (hereinafter '*Asocarne*'), paragraphs 31 and 32.

validity before the Court of First Instance.[26] The reasoning of the Court in *Gibraltar* does not distinguish between directives and regulations for the purpose of the assessment of their legislative character. The crucial question is 'whether or not the measure at issue is of general application'.[27] As I explain below, the same test clearly applies, in my view, when determining the legal standard applicable to a claim for damages.

28. The Court has also held that measures which are of general application, and are, thus, of a legislative character, may, none the less, be of individual concern to certain interested economic agents, thereby permitting such persons to seek their annulment.[28] A case in point is *Codorniu* v *Council*. Codorniu, a Spanish producer of sparkling wines which held a graphic trade mark including the words 'Gran Cremant', was held to be individually concerned by a regulation which confined the use of the term 'crémant' to certain sparkling wines produced in France and Luxembourg. The regulation prevented Codorniu from using its mark, a situation which, from the point of view of the contested provision, differentiated it from all other traders.[29] The Court has subsequently explained that outcome by reference to the effect on Codorniu's 'specific rights'.[30] The most important aspect of that case, for present purposes, is that the Court acknowledged that the regulation at issue was, none the less, legislative in character.[31] However, no claim for damages was made. Thus, it is unnecessary to seek to distinguish *Codorniu* v *Council* from the present case.

29. It does not follow from the exceptional recognition of standing to seek the annulment of legislative measures that such measures can, by the same token, be treated as being administrative in character for the purposes of determining the applicable criteria for Community liability in an action for damages under Article 215, second indent, of the EC Treaty. The reasons for the grant of standing to natural and legal persons to bring annulment proceedings under Article 173 of the EC Treaty (now, after amendment, Article 230 EC) in respect of decisions addressed to them and other acts of direct and individual concern to them differ from those for

26 — See *Flourez*, paragraph 11; *Asocarne*, paragraph 32. Although the Court expressly declined to address the question in *Asocarne*, the Court of First Instance has interpreted the judgments in *Gibraltar* and *Asocarne* as indicating that 'it is clear from the case-law ... that the mere fact that the contested measure is a directive is not sufficient to render such an action [for annulment] inadmissible' in Case T-135/96 *UEAPME* v *Council* [1998] ECR II-2335, paragraph 63.

27 — *Fedesa*, paragraph 27.

28 — See Joined Cases 239/82 and 275/82 *Allied Corporation* v *Commission* [1984] ECR 1005, paragraph 11; Case C-358/89 *Extramet Industrie* v *Council* [1991] ECR I-2501, paragraphs 13 and 14; Case C-309/89 *Codorniu* v *Council* [1994] ECR I-1853, paragraphs 17 to 19; *Asocarne*, paragraph 43; Case C-87/95 P *CNPAAP* v *Council* [1996] ECR I-2003, paragraph 36; see also the judgment of the Court of First Instance in Joined Cases T-480/93 and T-483/93 *Antillean Rice Mills and Others* v *Commission* [1995] ECR II-2305, paragraph 66.

29 — Op. cit., paragraphs 17 to 22.

30 — *Asocarne*, paragraph 43; *CNPAAP* v *Council*, op. cit., paragraph 36.

31 — Op. cit., paragraph 19.

distinguishing between legislative and administrative measures in the context of actions for damages. The Court made a comparative survey of national laws in *HNL* v *Council and Commission*[32] and observed that public authorities in the Member States can only exceptionally and in very special circumstances incur liability for legislative measures which are the result of choices of economic policy, and continued:

'This restrictive view is explained by the consideration that the legislative authority, even where the validity of its measures is subject to judicial review, cannot always be hindered in making its decisions by the prospect of applications for damages whenever it has occasion to adopt legislative measures in the public interest which may adversely affect the interests of individuals.

It follows from these considerations that individuals may be required, in the sectors coming within the economic policy of the Community, to accept within reasonable limits certain harmful effects on their economic interests as a result of a legislative measure without being able to obtain compensation from public funds even if that measure has been declared null and void.'[33]

30. The Court has since made clear that the fact that an action by a natural or legal person for the *annulment* of a measure of general application is admissible because of its individual effects on that person does not mean that it will be treated as administrative in character in an action for damages by the same person. Thus, in *Sofrimport* v *Commission*,[34] the Court annulled in part certain Commission regulations at the suit of a closed group of importers whose goods were in transit to the Community when the regulations were adopted and whose interests should have been taken into account, but applied the test for liability in respect of legislative measures in the parallel action for damages. In *Antillean Rice Mills and Others* v *Commission*,[35] the Court of First Instance annulled part of a Commission decision addressed to the Member States at the suit of certain traders because, notwithstanding its legislative nature inasmuch as that decision applied to all the traders concerned, taken as a whole, it was of individual concern to the applicant traders (who had already entered into contracts) as persons whose interests the Commission was required to take into account. None the less, the Court confirmed on appeal the

32 — Joined Cases 83/76, 94/76, 4/77, 15/77 and 40/77 [1978] ECR 1209, paragraph 5.

33 — Ibid., paragraphs 5 and 6. The measure in question had already been declared void pursuant to a request for a preliminary ruling on this point in Case 114/76 *Bela-Mühle* v *Grows-Farm* [1977] ECR 1211.

34 — Case C-152/88 [1990] ECR I-2477, paragraphs 10 to 13 and 25.

35 — Op. cit. at footnote 28 above.

Court of First Instance's application to the parallel action for damages brought by the same traders of the liability criteria applicable to legislative measures.[36] The Court stated:

'The fact that the contested measure is in the form of a decision, and hence in principle capable of being the subject of an action for annulment, is not sufficient to preclude its being legislative in character. In the context of an action for damages, that character depends on the nature of the measure in question, not its form (see, to that effect, the *Sofrimport* judgment).'[37]

31. It is clear to me that the contested Directive is legislative in character in so far as it affects the present proceedings. As the Court of First Instance rightly observed, it is a measure of general application. It affects, by reference to generally prescribed objective criteria, all traders operating in the sector in question. Thus, undertakings such as Bioderma and Klorane, which the appellants state had at one stage produced and marketed sun products containing 5-MOP in contravention of Mr Goupil's claimed patent rights, were potentially affected just as much as Bergaderm. Had Mr Goupil licensed the right to produce and market sun products containing citric 5-MOP to a number of undertakings in the Community, all such undertakings would have been subject to the maximum-content prescriptions of the contested Directive. Distributors and retailers who held stocks of Bergasol at the moment when the prohibition on supply to the final consumer came into effect would also have been obliged to comply with its terms. Producers of sun products containing 5-MOP derived from non-citric sources would, had they existed, have been equally affected. Finally, the contested Directive in its current form will continue to apply to all producers of sun products after Mr Goupil's patent rights expire. In these circumstances, the fact that Bergaderm could, allegedly, be identified as the only producer undertaking to be immediately affected by the contested Directive does not suffice to deprive it of its legislative character. It is well established in the case-law that the fact that the number or even the identity of the persons to whom a legislative measure applies can be determined is not such as to call into question its legislative character.[38]

32. Such an outcome seems to me to be consistent with the above-quoted explanation of the different approaches to Community liability in respect of legislative and administrative measures. Just as in the case of the exercise of Community competences in the economic field, the protection of public health and the need to adapt rapidly

36 — Case C-390/95 P [1999] ECR I-769, paragraphs 56 to 61; see paragraphs 189 to 194 of the judgment of the Court of First Instance, op. cit.

37 — Op. cit., paragraph 60.

38 — See paragraph 50 of the contested judgment; *Gibraltar*, paragraph 17; *Asocarne*, paragraph 30.

to technical progress in order to pursue that objective [39] entails the exercise of broad discretion by the Commission. In particular, the Commission must be able to take protective measures against real risks to health where the existence or extent of danger is still uncertain and 'without having to wait until the reality and seriousness of those risks become fully apparent'. [40] Its freedom to adopt the general measures that seem necessary to address a threat to public health should not be hampered by the need to take account of possible claims for compensation by private parties whose economic interests — including their intellectual-property rights — may be affected in the event that those measures are tainted by any form of illegality.

33. Thus, there does not appear to me to be any reason to question the decision of the Court of First Instance to classify the contested Directive as a legislative measure of general application and I recommend that the Court reject the first ground of appeal.

C — *The second ground of appeal*

34. In my view, the first limb of the second ground of appeal is inadmissible, by virtue of Article 168a of the EC Treaty (now Article 225 EC) and Article 51 of the EC Statute of the Court of Justice, as it directly contests the Court of First Instance's finding of fact that there was nothing in the documents submitted to it to support the conclusion that the Commission misunderstood the scientific arguments concerning the risk posed by sun oil containing bergamot essence. [41] In any event, I can see no reason to criticise the conclusion of the Court of First Instance, based, in particular, on the Court's judgment in *Angelopharm* v *Hamburg*, [42] that the Commission was entitled to give effect to the opinion of the Scientific Committee.

35. As regards the second limb of this ground of appeal, the Court of First Instance did not, in my view, commit an error of law in invoking the precautionary principle already cited by the Court in *National Farmers' Union*. The argument based on that principle is, if anything, even more compelling in the circumstances of the present case. *National Farmers' Union* concerned an emergency measure temporarily banning cattle and beef exports from the United Kingdom because of uncertainty as to the risks posed by bovine spongiform encephalopathy (BSE) to human consumers of beef products. The measure referred expressly in its preamble to the need for additional detailed scientific study.

39 — See the third and ninth recitals in the preamble to the Cosmetics Directive.

40 — *National Farmers' Union*, op. cit. at footnote 18 above, especially paragraph 63.

41 — Paragraph 63 of the contested judgment.

42 — Loc. cit.

Although there is evidence of differences between members of the scientific community about the threat posed by the use of 5-MOP in sun products, the research undertaken was much more extensive, and over a much longer period, than that which preceded the adoption of the emergency measure at issue in *National Farmers' Union* and the recommendation made by the Scientific Committee was much more decisive. In the light of such persuasive evidence, the Commission was justified in opting to take protective measures without waiting for the scientific debate to be resolved to the satisfaction of all interested parties.

D — *The third ground of appeal*

36. This ground of appeal concerns alleged breaches by the Commission of superior rules of law for the protection of individuals. Since the contested Directive is a legislative measure, proof of such a breach is, as I have already said, essential to the success of the appellants' claim. The first limb relates to the Commission's alleged non-observance of the requirement that its proposal be submitted to the Council after the Adaptation Committee gave an unfavourable opinion on 1 June 1992. It is clear to me that non-compliance with Article 10 of the Cosmetics Directive, which sets out the relevant procedure, would not constitute such a breach of a superior rule as to impose liability for damages in respect of a legislative measure. Community-law rules on the interaction of the political institutions and of bodies such as the committees provided for in the Comitology Decision [43] are examples *par excellence* of rules regarding the division of powers. The Court stated in *Vreugdenhil* v *Commission* [44] that 'the aim of the system of the division of powers between the various Community institutions is to ensure that the balance between the institutions provided for in the Treaty is maintained, and not to protect individuals'. Thus, failure to observe that balance would not, on its own, be sufficient to engage the Community's liability to aggrieved individuals. [45]

37. In any event, I share the Court of First Instance's assessment that the Commission was entitled to withdraw its proposal in a situation where the members of the Adaptation Committee were evenly divided over the merits of two alternative proposals, and to submit a new proposal after further study. The appellants' case is based on an unduly literal reading of Article 10 of the Cosmetics Directive. It would be absurd if the fact that a particular type of measure can only be adopted by a prescribed procedure were held to imply that that procedure, once commenced, must be pur-

43 — Council Decision 87/373/EEC of 13 July 1987 laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ 1987 L 197, p. 33.

44 — Case C-282/90 [1992] ECR I-1937, paragraph 20.

45 — Ibid., paragraph 21.

sued to the end even if the party proposing the measure wishes to reconsider its appropriateness, or its chances of adoption, in the course of the procedure. The appellants' argument would entail that the Commission would be bound to adopt measures which it no longer favoured in circumstances where both the Adaptation Committee and the Council failed to act. Article 189a of the EC Treaty (now Article 250 EC) provides that '[a]s long as the Council has not acted, the Commission may alter its proposal at any time during the procedures leading to the adoption of a Community act'. There is nothing to suggest that this rule, which includes the possibility of withdrawing a proposal, does not apply to the adoption of Commission measures subject to the participation of committees in which the Member States are represented and/or of the Council. In *Pharos* v *Commission*, the Court stated, in relation to a legislative procedure materially identical to that provided for by Article 10 of the Cosmetics Directive, that 'where the measures proposed by the Commission are not in conformity with the opinion of the Adaptation Committee [on Veterinary Medicinal Products], or where no opinion is delivered, the Commission is not obliged to submit the same measures, without amendment, to the Council'.[46] By the same token, in the circumstances of the present case, the Commission could withdraw its proposal and submit a fresh one after further examination of the scientific issues by the Scientific Committee. I would therefore reject the appellants' arguments in this regard.

38. The second limb of this ground of appeal relates to the appellants' alleged right to be heard. The Court of First Instance found *as a fact* that the appellants had had ample opportunity to express their views to the Scientific Committee and the Commission and had been able to address the ad hoc group of experts, which apparently comprised the members of both the Scientific Committee and the Adaptation Committee. Their arguments are, therefore, inadmissible to the extent that they contest this finding. In so far as they may be taken to argue that they were entitled to an even greater degree of participation in the legislative procedure, they have not submitted any argument which would lead me even to doubt the analysis of the Court of First Instance, which accords with the Court's consistent case-law.

39. The third limb of this ground of appeal, regarding the participation of Swedish and Austrian representatives in the Adaptation Committee, is entirely and manifestly unmeritorious. New Member States are immediately entitled, in the absence of special conditions in the Act of Accession, to participate on a footing of equality with the other Member States in all the legislative activities of the Community.

46 — Case C-151/98 P [1999] ECR I-8157, paragraph 23. This is the appeal from Case T-105/96 *Pharos* v *Commission*, op. cit., cited by the Court of First Instance at paragraph 55 of the contested judgment. The cases differ in that interested parties may apply for measures to be adopted under the legislation at issue in the *Pharos* case, with the result that the requirement that proposals be submitted to the Council 'without delay' if they are not approved by the relevant Adaptation Committee does impose certain obligations on the Commission which, in my view, are absent in the present context.

40. The appellants' contention regarding breach of the principle of protection of legitimate expectations is new, and, thus, inadmissible by virtue of Article 113(2) of the Rules of Procedure of the Court of Justice. Its arguments regarding proportionality before the Court of First Instance and on appeal are substantially the same as those in respect of the Commission's alleged manifest error of assessment of the facts and were addressed together by the Court of First Instance. The appellants' pleadings on appeal on the proportionality point contain nothing liable to undermine my conclusion in respect of the second ground of appeal, namely that the Commission was entitled to give effect to the factual and scientific assessments of the Scientific Committee in order to protect public health. I recommend, therefore, that the Court also reject this aspect of the appeal as unfounded.

VII — Conclusion

41. In the light of the foregoing, I recommend that the Court:

(1) Reject the appeal; and

(2) Order the appellants to pay the costs.