incur, as a result of its default towards other Member States, the Community or private parties.

2. Directive 76/768 on the approximation of the laws of the Member States relating to cosmetic products has provided exhaustively for the harmonization of national rules on the packaging and labelling of those products. Accordingly, a Member State which subjects the marketing of cosmetic products to the lodging with the competent national authorities of a declaration containing information other than that which it may require under Article 7(3) of the directive and which requires that any manufacturer or person responsible for the marketing of a cosmetic product should keep at the seat of his undertaking in the Member State concerned a file for each product manufactured or imported containing all particulars relating to the composition, properties and description of the product, to the formal record of the manufacture and inspection of each batch and to the method adopted for such inspection, has failed to fulfil its obligations under the directive.

REPORT FOR THE HEARING
in Case C-29/90 *

I — Facts

Council Directive 76/768/EEC of 27 July 1976 (hereinafter referred to as 'the directive') seeks to approximate the laws of the Member States relating to cosmetic products. It defines the standards which the composition of cosmetic products must meet as well as their labelling and packaging. The aim of the approximation was to ensure the protection of public health and remove obstacles to trade resulting from differences in the laws of the Member States, in particular in relation to the requirements concerning the protection of public health.

Article 7(1) of the directive provides:

'Member States may not, for reasons related to the requirements laid down in this Directive and the Annexes thereto, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of this Directive and the Annexes thereto.'

Article 14 requires Member States to bring into force the provisions needed in order to comply with the directive within a period which, in the case of the Hellenic Republic, which is considered to be an addressee of

* Language of the case: Greek.

the directive pursuant to Article 143 of the Act of Accession of the Hellenic Republic, expired on 1 January 1981 pursuant to Article 145 of the Act of Accession.

The Hellenic Republic transposed the directive into its national law by Presidential Decree No 532 of May 1981. Article 2(1) of the presidential decree provides:

'Cosmetic products may be marketed only after the manufacturer or, in the case of imported products, the person responsible for marketing, has lodged a declaration with the KEEPH together with the following information and supporting documents:

(a) the name of the product;

(b) its form;

(c) its composition in terms of ingredients and their quantities;

(d) the name and address of the laboratory or the factory where it is made;

(e) the surname and first name and address of the person responsible for marketing;

(f) the physical and chemical constants and a description of the product;

(g) a specimen of the instructions for use;

(h) a speciman of the wording on the label or on each container.'

Article 5 of the decree is worded as follows:

'1. Every manufacturer or person responsible for marketing a cosmetic product must keep at the undertaking's head office in Greece a complete file for each manufactured or imported product, containing all particulars relating to the composition, in terms of ingredients and their quantities, physical and chemical constants and description of the product, to the formal record of the manufacture and inspection of each batch and to the method adopted for such inspection, so that the manufacturer or importer may be in a position, in the event of inspection by sample, of demonstrating the properties of the product.

2. . . .

3. If there is any alteration in the particulars contained in the original declaration and in the file referred to in paragraph 1, the person entitled to the product must lodge a fresh declaration . . . '.

On 11 November 1986 the Commission sent to the Hellenic Republic a letter of formal notice under Article 169 of the EEC Treaty. In the notice the Commission drew the attention of the Greek Government to the incompatibility of those requirements with the provisions of the directive and requested it to submit its observations.

The Greek Government replied by letter dated 23 February 1987. As regards the declaration by the manufacturer or importer, it proposed that the information to be supplied should be confined to the indispensable information, namely the composition, in terms of ingredients and their quantities, the physical and chemical constants, the packaging and the instructions for use. There should no longer be any requirement to maintain a file.

Since it considered that the proposals made by the Hellenic Republic were unsatisfactory, the Commission, on 25 October 1988, issued a reasoned opinion as provided for in Article 169 of the EEC Treaty. In the reasoned opinion the Commission took the view that, by requiring a declaration to be lodged together with certain information and a file to be started containing information which was either already on the packaging, the containers or the labels of the cosmetic products or was not justified in view of the speedy and appropriate therapeutical action in the event of difficulties, the Hellenic Republic had failed to fulfil its obligations under the directive, and in particular Article 7 thereof. The Commission allowed the Hellenic Republic a period of two months to comply with the reasoned opinion.

In its reply of 17 January 1989 the Hellenic Republic informed the Commission that it would deal as a matter of urgency with the amendments to Articles 2 and 5 of Presidential Decree No 532/81, taking into account the observations made by the Commission, and forwarded a draft amendment. The draft does not provide for the removal of the requirement to lodge a declaration but simply limits the information which it has to contain. Instead of requiring a file to be kept, the draft requires manufacturers or those responsible for the marketing of cosmetic products to make available to the National Board for Medicinal Products (EOPH) information on the ingredients.

The Hellenic Republic's reply did not satisfy the Commission, which brought the present action.

II — Procedure

The Commission's application was received at the Court Registry on 26 January 1990.

The written procedure followed the normal course.

Upon hearing the report of the Judge-Rapporteur, and the views of the Advocate-General, the Court decided to open the oral procedure without any preparatory inquiry.

III — Forms of order sought by the parties

The *Commission* claims that the Court should:

1. declare that the Hellenic Republic has failed to fulfil its obligations under Council Directive 76/768/EEC of 27 July 1976 on cosmetic products by requiring that such products may be marketed only if a declaration is made accompanied by information and supporting documents and if a file is kept

containing information which is already printed on the packaging, containers or labels of cosmetic products or which is not justified for the purposes of prompt or appropriate medical treatment in the event of difficulties;

2. order the Hellenic Republic to pay the costs.

The *Hellenic Republic* did not formally ask for any form of order.

IV — Pleas in law and arguments of the parties

The *Commission* claims that the aim of the approximation provided for by the directive was to ensure the protection of public health and to remove obstacles to trade resulting from differences between the laws of the Member States particularly in relation to the requirements for safeguarding public health.

The directive imposes precise requirements on the Member States in relation to the conditions which cosmetic products must satisfy in order to be authorized to be put into circulation on the domestic market. They include the requirement laid down in Article 7, which provides that the Member States may not refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of the directive.

By imposing, in Article 2 (1) and Article 5 of Presidential Decree No 532/81, obligations in addition to those laid down in the directive and by subjecting in particular the marketing of a cosmetic product to the prior lodging of a declaration with the competent authorities and to the keeping of a file at the seat of the manufacturer in Greece or of the person responsible for the marketing, the Hellenic Republic obstructs, prohibits or restricts the marketing of products which satisfy the requirements of the directive. In that respect it is not possible to allow a Member State to have recourse to a unilateral measure in order to increase the protection of man or the environment unless the directive expressly provides the possibility of doing so, which is not the position in the present case.

The draft law forwarded by the Hellenic Republic left untouched the requirement to lodge a prior declaration with the KEEPH but limited the particulars which had to be given.

Article 7(3) of the directive requires information to be supplied for reasons of public health, that is to say for the purpose of medical treatment in the event of difficulties. Article 2(2) of Presidential Decree No 532/81 covers all such cases. As regards the forwarding of information to the KEEPH for reasons of public health for which the draft amendment of Article 5 provides instead of requiring a file to be kept, the Commission considers that requirement to be unjustified.

The Commission concludes that the Hellenic Republic has not adopted the measures needed in order to comply with the provisions of the directive, and in particular Article 7.

The *Hellenic Republic* states that the competent departments of the Ministry for Health, Welfare and Social Security are preparing a draft ministerial order which will amend Presidential Decree No 532/81 in accordance with the directive and the Commission's observations.

J. L. Murray
Judge-Rapporteur