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Implications of the enlarged European Economic Community on the quality and safety of cosmetics and toiletries

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Synopsis—Prior to the enlargement of the EEC in January 1973, when Britain, Denmark and Ireland joined, there was already some activity relating to the Cosmetic and Toiletry Industry. A proposal for a 'Directive on the Approximation of the LAWS of Member States relating to Cosmetic Products', based on a negative, a restricted and a provisional list was being prepared. A Technical Study Group of Government experts had been formed to draw up the lists and a group of analysts assembled to recommend analytical methods to monitor the materials in the restricted and provisional lists. UK Government and Industrial representatives were included in these Groups and in addition a Microbiological group has been set up.

Several amendments to the draft Directive have been suggested and it is not likely to become law until 1975. There is a strong move by most member states towards a POSITIVE LIST but this could not be implemented for at least 5 years because of the immense difficulties which will have to be overcome.

In any case, the implications are that all companies manufacturing goods which come within the scope of the Directive will have to ensure that all their products offered for sale conform to the legislation. Details of the various lists and the proposed reference methods of analysis and control together with their implementation will be discussed.

In Britain, we have now become accustomed to the fact that we belong to the EEC but the implications as they relate to this industry are not always appreciated.

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At the beginning of 1973 when Britain, Denmark and Ireland joined the Community there was already under consideration a proposal for a Directive on the Approximation of the Laws of Member States relating to Cosmetic Products.

To simplify this title it will be referred to as the Cosmetics Directive. It is, however, of interest to note the exact wording of the full title which in effect means harmonization of existing legislation in the various states and not the creation of new laws.

Before entry, Britain had no specific legislation relating to cosmetics, but there were restrictions and recommendations, particularly in respect of hormones and certain therapeutic products, included in the 1968 Medicines Act and the 1972 Poisons Act.

None of the other members had legislative control either, but some had 'negative lists' of substances which were forbidden in all products offered for general sale.

The draft Directive had taken some years to prepare. The responsible Commissioner was Mr A. Spinelli of Italy, and the preparation of the Directive came under the Directorate General for Industrial, Technological and Scientific Affairs. In the early part of 1973, just after the enlargement of the EEC, responsibility was transferred to another Directorate General, namely The Internal Market and Harmonization of Legislation under the control of Mr F. O. Gundelach of Denmark.

At the end of 1972 the Draft Directive was submitted to the Council of Ministers, also to the Economic and Social Committee and the European Parliament for comment. Recommendations and resolutions from the latter two bodies have been received and are being considered with the main Directive by the Council of Ministers. It will then be rediscussed by Government experts and finally by the permanent representatives from the Member States. When the Directive is evenually agreed it will be binding but discretion is left to the National Authorities.

The contents of the draft Cosmetics Directive are appended in an abridged form. They include 15 articles embracing the scope of the proposal and the following Annexes.

Annex I—list of products regarded as cosmetics.

Annex II—a 'negative list' of 425 substances that must not be used.

Annex III—a 'restricted list' of substances.

Annex IV—a 'provisional list' of substances.

Annex V—a list of substances excluded from the Directive (only hormones and selenium disulphide are included at present).

I propose to highlight those parts which relate to Quality and Safety.

Article 2 states that 'Cosmetic products put on the market within the Community must not be capable of causing damage to human health when they are applied as directed'. The bland kind of statement with its complete lack of definition leaves many unanswered questions. For example: What are the criteria for damage to human health? . . . How should this be tested? . . . Should animals or human subjects be used? . . . How many should be tested? . . . What protocol should be used? . . . How should results be interpreted? . . . etc. etc. It will undoubtedly be the responsibility of the manufacturer to provide evidence that his product cannot cause damage to human health but no guidance or recommendations about the way this should be done are available. So for the time being the manufacturer continues to meet his own criteria regarding the safety of his product when used as directed.

Article 3 states that 'Member States shall take all the necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive and its Annexes can be put on the market', and *Article 4* says that 'Member States shall prohibit the marketing of cosmetic products containing (a) the Substances in Annex II, (b) and (c) the substances in Annex III part 1 and 2 outside the limits and conditions fixed'. There is an EEC committee of analysts whose task is to recommend reference methods for checking whether products comply with the restrictions laid down in Annex III, but there is little indication that ways of detecting the possible presence of the long list of substances in Annex II will ever be considered. This must imply that the manufacturer is put on trust not to include any of these substances. It does not require much imagination to envisage the insuperable problems which could be created by an over-zealous Member State.

Then we come to the Provisional List (Annex IV). This is covered by *Article 5* which states that 'For a period of 3 years . . . Member States shall accept marketing of cosmetic products containing the substances in Annex IV parts 1 and 2'.

The same analytical committee is considering reference methods for products containing substances in this Annex. But what happens at the end of three years? This is covered in *Article 9* part 3: 'On the basis of the results of scientific and technical research the substance provisionally accepted shall at the end of three years be

—Finally included in Annex II or III

—or kept for a further period of 3 years in Annex IV

—or removed from any Annex to this Directive.'

So far there is no indication which criteria will be used to decide the fate of Annex IV substances. Is it the duty of the cosmetic manufacturer, the ingredient manufacturer or some other body to furnish evidence on which judgement can be made? Considerable costs could be incurred in checking a particular substance only to find that some other kind of information is needed.

Article 6 relates to labelling and advertising and this involves both Quality and Safety. Point 3 in this article states that special precautions of use must appear legibly on the container or, if this is impossible, on the outer pack and the enclosed leaflet.

In Annexes III and IV there are columns headed 'Conditions of use and warnings to be printed on the label'. Not all substances have a requirement of this type, but for those where it is necessary it can be quite wordy. For example, for diamino-benzenes, -toluenes and -phenols it is as follows: 'Can cause an allergic reaction (in persons sensitive to it). Requires a patch test (behind the ear or on the inside of the elbow) at least 24 hours before application. Add particulars of the method of making the patch test.'

So the manufacturer must make sure he has room to put this warning on the container or on the package and leaflet and that it is legible, which we must take to mean that the print size is large enough to be read without difficulty.

The fourth point of Article 6, although mainly concerned with advertising, is related to quality in that the manufacturer must not attribute characteristics to his products unless there is suitable scientific evidence.

In Britain we are already familiar with this requirement in the Trades Descriptions Act of 1968 and most manufacturers have already taken steps to ensure that they can back up their claims.

Article 8 is concerned with the supervision needed to ensure that cosmetic products conform to the provisions of the Directive. The responsibility lies with the Member States and so far there is no indication about how much effort will be devoted to this task or how it will vary from country to country.

I have already referred to *Article 9* when discussing Articles 4 and 5. The first paragraph of the first point requires procedures for the sampling and analysis of products containing substances in Annexes III and IV and the analytical committee are actively working towards this goal.

The second paragraph of the first point refers to bacteriological purity and a committee has recently been formed to decide on criteria and methods to ensure that products are acceptable in this respect.

Article 10 provides for the formation of a Committee of Adaptation. This committee will not be set up until the Directive is finally accepted but there is no doubt that it will be very necessary and will probably have a full programme of work. The methods recommended by the analytical committee will have taken into account most of the important factors and they will have been checked against a selection of relevant products on the market but it would be impossible to check every product from every country. This means that there could be some products which are not amenable to testing by the reference method. The onus is on the manufacturer to check whether his product gives the correct answer when tested according to the reference method. If it does not then he must bring this to the attention of the Committee of Adaptation using the mechanism outlined in Article 11.

Article 12 is of interest in that it allows for the possibility that a product could constitute a danger to human health even though it conforms to the Directive. Member States who find such products can forbid their sale in their territory for one year and they must inform the other Member States and the Commission, detailing the reasons. The Commission must start consultations within 6 weeks and eventually decide if the Directive must be revised.

Finally, *Article 14* states that when the Directive is finally agreed, all Member States must make the necessary provisions to ensure compliance within 18 months.

To summarize, the main points arising from this Directive are as follows.

(1) Products must not cause damage to human health.
(2) No product can be marketed if it contains any substance listed in Annex II.
(3) Products containing substances in Annex III must conform to the restrictions and conditions laid down.
(4) Products containing substances in Annex IV must also conform to the restrictions and conditions laid down, but at the end of 3 years their use will be reviewed in the light of any new safety data which is available.
(5) Products must be correctly labelled and claims must be justifiable.
(6) Reference methods will be published for the sampling and analysis of products containing substances in Annexes III and IV together with methods for checking bacteriological purity of all cosmetic products. Manufacturers must check that their products can be

analysed by these methods and if not they must bring the matter to the Committee of Adaptation.

(7) Any alterations or amendments to the Directive which individuals feel should be considered can be put forward according to the mechanism in Article 11.

(8) If a product, even though it conforms to the Directive, is found to be harmful, its sale can be forbidden.

(9) Within 18 months of acceptance of this Directive provisions will be introduced to ensure that all cosmetic products conform to the requirements of the Directive.

Present situation

Recommendations from the Economic and Social Committee and resolutions from the European Parliament are still being discussed by the Council of Ministers and the Directive is unlikely to be finalized this year (1974).

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Appendix

Proposal for a council directive on the approximation of the laws of the member states relating to cosmetic products

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Brussels 6th October 1972
Abridged version

Explanatory memorandum

(1) *General*

A comparative study of the laws, regulations, etc., in force in the Member States revealed divergences and the object of the Directive is to eliminate these divergences. The Commission formed a working party of experts and a technical study group, with provision for European representatives of Co-li-pa, to express their points of view on the technical problems.

(2) *Harmonization solution*

The Directive is based on harmonization and the result will be the substitution of Community provisions for the national laws in force.

(3) *Notes on the proposal*

These cover the scope of the Directive as exemplified by the 15 Articles and 5 Annexes. The system chosen is based on negative listing: conconsequently all substances not specifically prohibited are accepted, so any cosmetic product is accepted providing it does not contain any of the prohibited substances in Annex II and meets the restrictions laid down for any substance in Annex III and IV.

(4) *Acceding countries*

Technical contacts with the experts of acceding countries have been established.

(5) *Consultation of the European Parliament and the Economic and Social Committee*

The opinion of these bodies is necessary to comply with the provisions of Article 100 of the EEC Treaty of Rome. Application of the Directive will require amendments of the laws of all Member States.

The Directive

Article 1 (Definition of cosmetic)

'Cosmetic product' means any preparation intended to be placed in contact with superficial parts of the body or with teeth and mouth with a view principally for perfuming, cleaning, protecting, keeping in good condition, changing appearance or correcting body odours. Annex I lists cosmetic products included in the Directive. Annex V lists substances excluded from the Directive.

Article 2 (Products must not cause human damage)

Cosmetic products must not be capable of causing damage to human health when they are applied as directed.

Article 3 (To be marketed—the product must conform)

Member States shall take the necessary steps to ensure that only products conforming to the Directive and its Annexes are put on the market.

Article 4 (Prohibitions Annex II; Restrictions Annex III)

Member States shall prohibit the marketing of cosmetic products containing:

(a) the substances listed in Annex II;
(b) the substances listed in Annex III (part 1) outside the limits and conditions fixed;
(c) colourants other than those in Annex III (part 2) if the products are intended to be used near the eyes, on the lips or in the mouth.

Article 5 (Provisional Restrictions—Annex IV)

For a period of 3 years Member States shall accept marketing of cosmetic products containing

(a) substances listed in Annex IV part 1;
(b) colourants listed in Annex IV part 2 if these products are intended to be used near the eyes, on the lips or in the mouth.

Article 6 (Packaging and labelling requirements)

(1) The container or outside package must bear the name and address of the manufacturer/packer/importer/distributor having his registered place of business within the Community.

(2) The container or outside package shall state the net content at time of packing in legal metric units and expiry date for products which do not have an unlimited shelf life.

(3) Special precautions of use shall appear legibly on the container, or if impossible on the outside package and an enclosed leaflet.

(4) The use of names, trademarks, images or other signs suggesting a characteristic which the products do not possess is prohibited. A recommended amendment to this section includes prohibiting claims for products where there is no, or insufficient, scientific evidence.

Article 7 (Freedom of marketing to Member States)

Member States must not prohibit or hamper the marketing of products which conform to the Directive but they can demand that the particulars required in Article 6 are expressed in their national language(s).

Article 8 (Supervision)

Member States shall take the necessary measures to supervise that cosmetic products conform to the Directive.

Article 9 (Sampling, analysis, bacteriological criteria, amendments, fate of Annex IV substances)

(1) Procedures for sampling and analytical methods necessary for supervision are determined in accordance with Article 11. Similarly, criteria for bacteriological purity.

(2) Amendments necessary for the adaptation of Annexes II and III shall be adopted in accordance with the same procedure.

(3) On the basis of results of scientific and technical research the substances and colourants provisionally accepted in Annex IV shall at the end of the 3-year period provided for in Article 5 be:

—finally included in Annex II or III;

—or kept for 3 more years in Annex IV;

—or be removed from any Annex to this Directive.

Article 10 (Committee for Adaptation)

A Committee of Adaptation shall be established, composed of representatives from Member States and chaired by a representative of the Commission.

Article 11 (Mechanism for raising matters)

(1) In cases where reference is made to the procedure the matter is brought before the Committee of Adaptation by the chairman, either on his own initiative or at the request of a representative of a Member State.

(2) The chairman shall submit a draft of the measures to be taken. The Committee of Adaptation shall give its opinion within the time fixed by the chairman and decide by a majority of 12 votes according to the weighting laid down in Article 148 of the Treaty. The chairman shall not take part in the vote.

(3) (a) When the Committee of Adaptation is in accord the Commission shall lay down the proposed measures.

(b) If not, or in the absence of an opinion from this Committee, the Commission shall forward to the Council a proposal concerning the measures to be taken and the Council shall act by a qualified majority.

(c) If after 3 months the Council has not acted, the measures proposed shall be adopted by the Commission.

Article 12 (Procedure when conforming products are found to be harmful)

(1) If a Member State ascertains that a cosmetic product presents a danger to human health, although it conforms to the Directive, that State,

in accordance with the procedure in Article 11, can provisionally restrict or prohibit the sale on its territory. At the same time it must communicate to the other Member States and the Commission the measures envisaged and the reason for the decision. (A likely amendment limits the time to 1 year.)

(2) If after 30 days no measure has been laid down by the Commission or the Council, the Member State may take the measures envisaged until such time as a decision is made according to Article 11. (A likely amendment requires the Commission to start consultations within 6 weeks and if the Directive has to be revised this must be completed within 1 year.)

Article 13 (Possible restrictions by Member States)

Precise reasons shall be stated for any individual measure taken to restrict or ban the marketing of cosmetic products. These shall be communicated to the interested party together with particulars of remedies available under the legislation in force in the Member States and the time limit for the proceedings.

Article 14 (Date for compliance)

(1) Within 18 months of notification the Member States shall introduce the provisions necessary to comply with the Directive and shall inform the Commission forthwith.

(2) Member States shall ensure that the text of such provisions of national law as they adopt in the field governed by this Directive is communicated to the Commission.

Article 15

The Directive is addressed to the Member States.