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COMMUNITY ACTION TO PROTECT THE CONSUMER IN THE FIELD OF COSMETICS

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INTRODUCTION

A large percentage of cosmetic products would be regarded by most people as essential. Soap, toothpaste, shampoo and talcum powder are products that are considered cosmetic. Anything that is not designed to heal and which is applied to the skin, hair, nails and lips is generally regarded as cosmetic.

The cosmetics industry is a flourishing one. Annual growth, by volume, averages about 10% in the Nine. Consumers are offered an increasing range of perfumes, soaps, cleansing creams and make-up. Advertising campaigns are launched that would make even the most hardened consumer without an underarm deodorant feel a social outcast. The range of products offered affect everyone from the cradle to old age. Many consumers, especially women, will pay a few pounds for a cosmetic product worth only a few pence. How can they be expected to know if the cosmetics they use are worth the money, let alone be sure they are safe to use. The list of ingredients contained in a product is usually baffling to all but the qualified chemist and indecipherable to the average consumer.

The line between cosmetics and medicaments is a fine one. If fluorinated toothpaste were called a medicament it could only be sold through chemists and its use would therefore be restricted. But the level of fluoride contained is safe. A person would have to eat two or three tubes of fluorinated toothpaste a day for some time before coming to any harm. Yet many cosmetic products contain far more dangerous chemicals than most medicines or drugs which are far more stringently regulated than such potentially harmful products as antiseptic creams and lotions, drops

for bloodshot eyes and acne creams, etc. These make it compulsory to print the required warnings both on the package and where practical on the actual container. If the latter is not practical, warnings go on a separate piece of paper attached to the container. Publicity suggesting characteristics that have not been scientifically proven is also banned.

Cosmetics are looked upon as a bit unnatural - we ought to know more about them. Many people tend to feel that cosmetics should be controlled for the very reason that they are applied directly to the human body.

The death of 22 babies in France in 1972 after being exposed to talcum powder containing an excess of hexachlorophene aroused suspicion about chemicals used in cosmetics and demonstrated the need for more effective safety measures. Only a year later the Belgian consumer magazine "Test Achats" analysed nine vaginal deodorants on sale and found five of them to contain hexachlorophene and all of them to be expensive, dangerous and totally ineffective.

The use of hexachlorophene in cosmetics is severely restricted by an EEC directive that will come into force in Community countries at the beginning of 1978.

NATIONAL LEGISLATION

Twenty-two young children died between May and August 1972 in the French regions of Aube and the Ardennes after contact with the talcum powder Morhange. At the same time there were similar cases in other regions of children between one and two years old with neurological problems as well as a case of irreversible paralysis. Investigations revealed the culprit, beyond doubt, to be Morhange talc. It contained an abnormally high content of hexachlorophene - samples showed at least 6%. Hexachlorophene is an efficient and powerful antiseptic and has been used for a long time to deal with bacteria. It has never been possible to eliminate its known toxicity. In small doses the substance would not have caused any harm. According to the manufacturer concerned, the formula for the talc did not even contain hexachlorophene.

The Morhange affair revealed a weakness in the legislation on hygiene and beauty products. They escape the checks and controls that medicaments are subjected to. A simple check at the end of the Morhange production line would have revealed the mistake.

The French government intended to legislate as a result of public outrage over Morhange. The case sparked off public concern in other countries. The UK, Denmark and Ireland also decided to act. Consumers deplored the absence of control. The decision of the French government and clamour for more stringent regulations provided the impetus for the Community to come up with proposals for a directive on regulating cosmetic labelling and contents.

The cosmetics industry felt unjustly accused. A production error, in their eyes, did not justify such furore aimed at it. Given the establishment of the free movement of goods between Community countries, the threat to the population is worrying. Public pressure on one national government could force frontiers to close for fear of suspect products from other countries. If suspicion were unfounded, manufacturers might find themselves the innocent victims of public fear and mass hysteria. Free trade within the Community is a goal that includes harmonising national safety regulations on cosmetics. And consumers should have the same protection as products. It would amount to a barrier to free trade if the regulations were not coordinated at Community level. The European Commission's idea was to extend the benefits of the proposed French legislation to all other Member States. One of the good aspects of a Community directive was that since cosmetics cross frontiers and people tend to buy them in other countries when they are on holiday, these people should have a good standard of protection wherever they go throughout the Community and not just in their own country.

The discussion of this directive at the Community level enabled a sharing of the various national sources of scientific information on which the different national legislations were based. This resulted in an improved overall level of protection. From the commercial point of view the adoption of the directive enables manufacturers to offer a wider choice to the consumer whilst at the same time defining economies in production by eliminating unnecessary differences between products marketed in various countries.

Ten years ago the regulations concerning cosmetic products in EEC countries were scattered about in a variety of legal texts dealing with food . . . and tobacco. Since then the majority of the EEC countries have been working on various legal proposals, specifically dealing with cosmetics. Belgium introduced a royal decree in May 1973 which was modified in March 1974. Other countries are still in the drafting stage. A Community directive was an opportunity to coordinate, harmonise and bring these regulations together.

The Community directive was urgent, to prevent the anarchic growth of national legislation. A study of the various legal provisions and regulations in force in European Community countries dealing with cosmetics has brought to light a number of divergences not only in technical provisions concerning composition and the use of certain additives (substances and colourants used in production) but also in the legal systems applied and definitions of the field of application whether covered by foodstuffs or pharmaceutical law. This obliges cosmetic producers to adapt their production techniques to the countries where their products are exported to. Member States have a duty, under the directive, to carry out controls and checks.

Since all legislation is based on the state's responsibility to protect consumers, the users of the products in question, differences from country to country only have a negative effect from the point of view of human health and the marketing of products. The most effective way of removing these negative effects was to coordinate the work being done at a national level by means of a Community directive.

THE COMMUNITY SOLUTION

The European Commission first submitted proposals for a directive harmonising laws in Member States on cosmetic products in October 1972. The proposed modifications to the draft represented the first major victory for consumers, who up until enlargement, took a restricted interest in the EEC. The directive was adopted by the Nine in July 1976 and will come into force in January 1978. The Commission's biggest job was defining what is meant by a cosmetic product, listing substances which may never be used in production, those which are definitely permitted and those substances subject to severe restrictions. This work is still not finished.

The aim of the directive is to eliminate the differences in national legislation on the labelling and the technical provisions on composition and permitted substances in the preparation of cosmetic products and on checking and control methods. When it is implemented the directive will take the place of national legal provisions. Member States will be obliged to prevent cosmetic products from being marketed which do not conform to the directive. They would have to accept trade in cosmetics which conforms to the EEC provisions in composition, packaging and labelling without any restrictions. The directive will thus encourage intra-Community trade and guarantee greater consumer protection. The directive is not so much aimed at big firms, but at smaller ones. Manufacturers would not, of course, intentionally introduce into cosmetics harmful ingredients, both from the point of view of legal liability and loss of reputation. But it is such a widely dispersed industry it is possible that manufacturers, especially small ones, are not technically well enough equipped to deal with these problems.

The directive defines what a cosmetic product is. And this is no easy problem. Defining a product such as rouge presents no problem. But in other cases it is not so easy to distinguish between cosmetics and medicaments. Some sun lotions, for instance, are designed to protect the skin against the sun. These are classified as cosmetics. Others are for treating sunburn. These are classified as medicaments. Some products contain both elements - many consumers prefer lotions which give protection from the sun while having a soothing effect. The line has got to be drawn somewhere.

Article 1 of the directive defines a cosmetic product as:

> "any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view to exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours."

Examples of the products to be considered as cosmetic products within the meaning of this definition are listed in Annex 1 of the directive. These are: creams, emulsions, lotions, gels and oils for the skin (hands, face,feet, etc.); face masks (with the exception of peeling products); tinted bases (liquids, pastes, powders); make-up powders, after-bath powders, hygienic powders, etc.; toilet soaps, deodorant soaps, etc.; perfumes, toilet waters and eau de Cologne; bath and shower preparations (salts, foams, oils, gels, etc.); depilatories; deodorants and anti-perspirants; hair care products: hair tints and bleaches, products for waving, straightening and fixing, setting

products, cleansing products (lotions, powders, shampoos), conditioning products (lotions, lacquers, brilliantines); shaving products (creams, foams, lotions, etc.); products for making up and removing make-up from the face and the eyes; products intended for application to the lips; products for care of the teeth and the mouth; products for nail care and make-up; products for external intimate hygiene; sunbathing products; products for tanning without sun; skin-whitening products; and anti-wrinkle products.

An important point for consumers contained in Article 2 is that cosmetic products put on the market must not be liable to cause damage to human health when they are applied under normal conditions of use. This is important since it requires a definition of what is harmful to human health and what isn't.

POSITIVE OR NEGATIVE LISTS:
THE BIG DEBATE

The Commission was faced with a number of approaches in drawing up the directive. Consumers demanded that instead of listing products cosmetics may not contain, which would imply that any new chemical appearing on the market could be used in cosmetics, the directive should list permitted products. Thanks to the European Parliament and the Economic and Social Committee, it will be possible to add lists of permitted substances through article 11 as soon as the test information on them is available. To declare a substance safe to health requires extensive testing and examination and the maximum of information. In practise this calls for innumerable tests and experiments. The degree of certainty needed to know if a substance is dangerous to health is easier to establish than the converse. Establishing a positive list is a long and onerous operation. Annexes three and four of the directive make up the first embryo positive list. For instance, mercury compounds are allowed in certain eye make-ups. As a preservative, mercury helps guard against cross-infection in use. If a product is on the positive list, that means it has been approved as not being dangerous. That does not, the Commission points out, mean the same as safe.

Annex three is a list of substances and colourants which cosmetic products must not contain except subject to the restrictions and conditions laid down, which includes conditions of use and warning which must be printed on the label in some cases. Some substances are prohibited in aerosols and others cannot be used in products for children under three years old. The Annex lays down the field of application and the maximum authorized concentration in the finished cosmetic product.

Similar restrictions are contained in Annex four which is a list of substances and colourants provisionally allowed. But their harmlessness has not been absolutely established. Toxicological tests are being carried out on these substances. Three years has been allowed for collecting supplementary information and revising this Annex. At the end of three years, these substances and colouring agents shall either be definitively permitted or definitively prohibited (Annex two) or retained for a further period of three years in Annex four or deleted from all Annexes to the directive.

The Commission also drew up a list of substances which should not be used in the manufacture of cosmetics. These substances, which are harmful to the body, are contained in Annex two - a negative list. All the major allergy provoking substances are in the forbidden list. Such a list cannot be exhaustive. There are numerous substances, on national poisons lists, which would be extremely dangerous if they were used in cosmetics. The negative list contains only substances that could be considered by the cosmetic industry in the manufacture of cosmetics that have been judged as dangerous to human health. The Commission originally opted for this solution to accelerate the process of getting the directive adopted by the Council of Ministers. There are 361 substances included in the list of substances which cosmetic products must not contain which forms Annex two of the directive. The numbers will change according to research.

The European Parliament had to be consulted on the Commission's proposals before they were able to be adopted by the Council. The Parliament encouraged rapid adoption of positive lists. The Economic and Social Committee took a similar viewpoint whilst admitting that drawing up such lists would not be without problem.

It was because of the opinions of these two European consultative bodies, together with pressure of public opinion, that Article 11 was included, making it possible to add positive lists to the directive.

The directive was modified in other ways following the Parliament's opinion. Several substances were added to the negative list. Certain provisions regarding labelling and sales and presentation of cosmetics were added.

While the European Parliament, the Economic and Social Committee, public opinion and most government authorities are in favour of positive lists, industry is not. Cosmetics and perfume manufacturers have opposed the initiative. Their main objection is that it will hold back expansion without bringing any real guaranteed safety to the consumer.

The research laboratories of these cosmetic firms are constantly developing new substances to improve their products which are tested before being put on the market. Registering these products on the positive list would require substantial expenditure and time delay. And it would be very difficult for manufacturers to protect their products through patents. The same argument is used against the obligation to label the products with certain ingredients if they are used. Manufacturers argue that to reveal the ingredients would be to give away trade secrets; the consumers claim that all products on the market are carefully analysed by their rivals. For testing, analysis and sampling cosmetics, the Committee for adaptation to technical progress - set up at the time the directive was adopted - is collaborating with industry to establish analytical methods in order to use its extensive experience in this field.

Manufacturers already have information on the different types of sampling for analysis, the different methods and processes for extracting the principal ingredients, and the different methods of identification of the principal ingredients.

CONCLUSION

The directive satisfies the consumer need for adequate protection and gives producers the legal base to develop their research plans and export and import within the EEC without fear of restriction as long as they adhere to the directive. The provisions on labelling contained in the directive are far reaching for consumers. While the directive will come into force at the beginning of 1978, cosmetic products that do not conform to its requirements will still be marketed in the Community for another two years.

The directive will align EEC legislation with that of the USA which is broadly similar. This is highly important considering the number of American products on the EEC market.