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QUALITY CONTROL FOR THE CONSUMER'S PROTECTION

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Synopsis

The protection of consumer cannot based only on necessary controls of government laboratories, because only analysis of raw materials and finished products, performed routinely, can provide some kind of protection against potentially dangerous contaminants or mistakes. European legislation will increase the necessity to manufacture quality cosmetic products in the near future. Directive 85/374 which is not yet ratified by all EC-members stresses product liability, putting the manufacture of "dangerous" and inferior products at considerable risk. In addition, changes in Council Directive 76/768 are presently being discussed that aim to legally impose some form of Q.C. and G.M.P. Of course many cosmetic manufacturers already practice G.M.P., especially the larger companies can efford to run a Q.C. labo ratory for raw-material validation and the control of finished products. Standard protocols for the control of raw materials, abudantly available in many pharmacopeias for the pharmaceutical industry, are scarce for most cosmetic ingredient. Attempts to provide these have been made by CTFA, the French industry association and UNIPRO.
It seems that cosmetic industry will probably follow the lead of pharmaceutical industry. Both the increasing scale of production, which makes production mistakes costly, as well as pressure from governments will move G.M.P. eventually inevitable, even if it is not legally imposed.

Riassunto

La protezione del consumatore non può essere affidata solo ai controlli dei laboratori pubblici, poiché solo l'analisi routinaria, effettuata nell'industria, di prodotti finiti e di materie prime può fornire una qualche forma di protezione nei confronti di errori e di contaminanti potenzialmente pericolosi. La legislazione europea d'altro canto sottolinea la necessità di produrre cosmetici, sempre più di qualità: la Direttiva 85/374, per esempio, evidenzia tra l'altro la responsabilità del produttore. In aggiunta le proposte di modifica della Direttiva 76/768, attualmente in discussione, introdnrranno, nella produzione industriale, alcune forme di controllo di qualità e norme di buona fabbricazione.
Certamente la maggior parte delle industrie cosmetiche, specie quelle più grandi, già hanno impostato laboratori di controllo per la verifica della qualità di materie prime e prodotti finiti. È da tenere poi in conto la scarsezza di informazioni di materie prime di interesse cosmetico, specie se confron-

tate con quelle di campo farmaceutico, malgrado gli sforzi fatti dal CTFA, dall'associazione delle industrie francesi e dall'UNIPRO.
Sembra inevitabile comunque che il futuro dell'Industria cosmetica debba in qualche modo essere simile a quello dell'Industria farmaceutica.

Introduction

The explicit demand by consumers and industry for safe and guaranteed products is increasing the importance of quality control within companies. Such control, along with compliance control - carried out by competent State authorities - is the only form of protection for the consumer. In recent years, turnover for the cosmetic industry in the EC has considerably increased. Also further development is expected soon with the opening of other markets. This will imply, for example, an increase in the size of industrial operations. Therefore, production will need to be more thoroughly controlled to prevent low-quality cosmetic products from reaching the market.

The increasing attention focused on environmental problems by governments and public opinion has led many people to lose confidence in chemistry and its products (as indicated by the enormous demand for the so-called, natural cosmetic products). Furthermore, mass media have alarmed public opinion when traces of carcinogenic substances - or substances considered as such - are found in a cosmetic. To face such calamities, quality control is the only form of protection for industry. Besides, in the near future, EC laws will put even more pressure on industry in order to obtain an ever more rigourous production. Directive no. 85/374, - which has not yet been ratified by all member states - underlines the manufacturer liability, imposing heavy sanctions on low-quality production. Moreover, the changes presently proposed to Directive 76/768 will legally enforce several forms of quality control and good manufacturing procedures (GMP) by the cosmetic industry.

Analytical chemistry appears basic for maintenance of the quality of a product and its importance will increase.

It is, however, a double-edged weapon. On the one hand, it makes it possible to determine the presence of substances at levels which were unthinkable only ten years ago. On the other hand, it can also often create unjustified alarm. Only the analysis of raw materials and finished products can protect against undesired substances and it is in the common interest of producer and consumer to do everything possible to guarantee safety of the finished product.

We will now examine, in detail, some points which are particularly important in this context.

Legislative aspects

Laws on cosmetic products are based on Directive no. 76/768 which regulates safety through a system of positive and negative lists. Positive lists include preservatives, sun filters and dyes. In spite of many obstacles, a list for antioxiders and hair dyes is expected soon.

The changes currently proposed to the Directive contain many innovations such as an obligation for the manufacturer to keep complete documentation of the entire production. This must include a description of production processes according to GMPs, and information about and specification of every raw material and all available data on undesirable effects which have followed the use of finished products. This means that some aspects of GMP must be added to the Directive.

These proposals are not expected to be approved without changes. However, they show the trend that will affect future EC laws.

GMP

Good manufacturing procedures and quality control have already been applied in the pharmaceutical industry on a large scale. This industry deals with highly active compounds, where mistakes or low quality cause great damage.

In this field, both raw materials and finished products are routinely tested, according to validated specifications.

The cosmetic industry will probably follow the

path of pharmaceutical industry because production is increasing and because of health policies which will impose the introduction of good manufacturing procedures.
Many cosmetic companies, especially the large industries, are certainly already using such procedures.
They are investing resources in laboratory quality control to validate raw materials as well as finished products and eliminate wastage.
Smaller companies will have many difficulties in adopting there procedures, such as, for example, the cost of analytical equipment or specialized staff. Therefore, they will often find it more convenient to rely on other laboratories, which, in many cases do not bave any deep experience in this field.
Another problem concerns raw materials which in many pharmacopeias are only described if they have pharmaceutical value; information is lacking if they have only cosmetic value. Extremely useful efforts have been made by the CTFA of the association of French industrialists and recently by UNIPRO, which has listed over 6,000 ingredients in its dictionary.

The EC and the control of cosmetic products

The control of cosmetic products is assigned by the EC to the single national authorities by establishing official analytical methods. In this regard, in 1971 the EC Commission set up a working group - called "Methods for the analysis of cosmetic products" - made up of experts from each member state, COLIPA and laboratory researchers who assist the Commission Secretariat. The aim is to develop the official analytical methodologies for the control of cosmetic products, as provided by art. of the EC Directive n. 76/768.
Since its creation there have been 32 plenary sessions and many meetings of subgroups.
The present directive presents seven annexes classifying temporarily permitted cosmetic ingredients, with restrictions and prohibitions. About 200 permitted and 400 prohibited substances have been identified in all.
At present, 29 methods bave been published and have therefore become official, and about ten others are in process. it is obvious that much is still to be done, not only because many substances bave not yet been studied, but especially because the designing of a method by the group is complicated. The procedure can be described as follows:
- the design and analytical method;
- a series of feasability studies in the laboratory;
- discussion and approval of the method in plenary session, preparation of the appropriate samples and carrying out of a cooperative study;
- assessment of the results; either final approval or modification of the method requiring a second collaborative test;
- final approval of the method and publication.

The 29 published methods can be applied to the substances listed in annexes III and IV. The methods use traditional techniques, such as titrimetry, gravimetry, colorimetry; some use GLC and TLC/GLC techniques; only one uses atomic absorption spectroscopy; most recent methods use TLC/HPLC techniques.
Currently, there is great need for methods for application to preservatives, dyes, solar filters, oxidation dyes and other classes of compounds.
Today, chromatographic techniques provide the solution to a great number of problems, but more updated techniques are going to be applied in the near future to face specific problems. This could create a situation in which only specialized laboratories would be allowed to make highly sophisticated analyses.

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