Comparative Study on Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products

Final Report

Contract No.: FIF.20030624

prepared for
European Commission
DG Enterprise

RPA

August 2004

Comparative Study on Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products

Final Report – August 2004

prepared for

European Commission, DG Enterprise

by

Risk & Policy Analysts Limited,
Farthing Green House, 1 Beccles Road, Loddon, Norfolk, NR14 6LT, UK
Tel: +44 1508 528465 Fax: +44 1508 520758
Email: post@rpaltd.demon.co.uk
Web: www.rpaltd.co.uk

RPA REPORT - ASSURED QUALITY	
Project: Ref/Title	J457/Cosmetics
Approach:	In accordance with Project Specification and associated discussions
Report Status:	Final Report
Prepared by:	Dr Jan Vernon, Business Development Director, RPA Tobe A. Nwaogu, Researcher, RPA
Approved for issue by:	Meg Postle, Director, RPA
Date:	3 August 2004

CONTENTS

GLOSSARY OF ACRONYMS

ANMAT	National Administration of Pharmaceuticals, Food and Medical Technology (Argentina)
ANVISA	Agéncia Nacional de Vigiláncia Sanitaria (Brazil)
ASEAN	Association of South East Asia Nations
CMR	Carcinogenic, Mutagenic and Reprotoxic
CIR	Cosmetic Ingredient Review
Colipa	European Cosmetic, Toiletry and Perfumery Association
CCTFA	Canadian Cosmetics, Toiletries and Fragrances Association
CTFA	Cosmetics, Toiletries and Fragrances Association (USA)
DIN	Drug Identification Number
FD&C Act	US Food, Drugs and Cosmetics Act
GAQSIQ	General Administration of Quality Supervision, Inspection and Quarantine (China)
GMP	Good Manufacturing Practice
INCI	International Nomenclature of Cosmetics Ingredients
ISO	International Standards Organisation
JCIA	Japanese Cosmetics Industry Association
MHLW	Ministry of Health, Labour and Welfare
MoH	Ministry of Health
MOU	Memorandum of Understanding
MRA	Mutual Recognition Agreement
NAFTA	North American Free Trade Agreement
OECD	Organisation for Economic Cooperation and Development
OTC	Over-the-counter
PAL	Pharmaceutical Affairs Law
PAO	Period After Opening
PIF	Product Information File
REACH	Registration, Evaluation, Authorisation and Restriction of CHemicals
SCCNFP	Scientific Committee of Cosmetics and Non-Food Products Intended for Consumers
SFDA	State Food and Drug Agency (China)
UK	United Kingdom
US FDA	United States Food and Drug Administration
UV	Ultra Violet
VCRP	Voluntary Cosmetic Registration Program

PART I

EXECUTIVE SUMMARY

I. Background

The manufacture, distribution and sale of cosmetics is a global industry within which the EU is a major player. The EU market for cosmetics is larger than the US market and twice the size of the market in Japan. Although data are not comprehensive, the value of output of the EU cosmetics industry is estimated at around €35 billion in 2001, employing over 150,000 Europeans directly.

Cosmetic products are subject to regulatory controls in all markets, in order to ensure the safety of products and avoid adverse impacts on the health of users. In the EU, the regulatory framework is provided by the Cosmetics Directive (76/768/EEC) and its subsequent amendments. Regulatory frameworks differ significantly between the different markets and are far from being harmonised. This has the potential for impacts on the competitiveness and economic viability of the industry. The inability to sell similar products across all markets, or the requirement to change test methods, formulations, packaging and advertising, can increase costs for the sector. Delays and high costs associated with the introduction of new ingredients and products can also reduce the potential for market growth.

To address these issues, the European Commission's Directorate-General Enterprise contracted Risk & Policy Analysts Limited to undertake a comprehensive study to:

- explore the different approaches taken to the regulation of cosmetics in different markets;
- identify the similarities and divergences at the international level;
- analyse the impacts associated with these; and
- make recommendations on the prospects and advantages of a harmonised approach.

The Technical Specification for the study is reproduced in Annex 1.

The study was carried out in close co-operation with the EU cosmetics industry, which participated in a study Steering Group at the invitation of the Directorate-General Enterprise, arranged workshops to provide information on similarities and divergences in regulation and submitted case studies to illustrate the impacts of regulatory approaches. Valuable input to the study was also provided by industry associations in other major and emerging markets, regulators inside and outside the EU and representatives of consumers.

II. Regulatory Frameworks for Cosmetic Products

Frameworks in the Major Markets

Current regulatory frameworks for cosmetics in the major markets (the EU, USA, Japan and Canada) follow two broad models:

- a **broad definition** of cosmetics, with safety ensured through controls over ingredients in the form of positive lists, prohibited and restricted lists, specific requirements concerning safety testing and maintenance of data files on safety. This is broadly the model of regulation in the **EU**; and

- a **narrow definition** of cosmetics, with few restrictions on the ingredients that can be used and the type of safety testing to be undertaken is determined by manufacturers. Products that do not meet the definition of cosmetics, often on the basis of claims made rather than composition, are **regulated as drugs**. This is broadly the model of regulation in the **USA** (although in the USA, products can be categorised as both cosmetics and drugs and subject to both sets of regulations).

Regulations in Japan and Canada are somewhat between these two models. **Canada** is closer to the US model but with a longer list of prohibited or restricted ingredients for cosmetics. **Japan** is closer to the EU model, but has an additional product category of **quasi-drugs**; the regulation of these is less onerous than for drugs but still requires pre-market approval and registration of ingredients.

Specific products may be categorised as cosmetics in one market and as drugs or quasi-drugs in other markets. Examples of different categorisation of products are illustrated in Table 1.

Table 1: Illustrative Examples of Product Categorisation in Different Markets

Product Type[1]	**Market**			
	EU	**USA**	**Japan**	**Canada**
Soap for hands	Cosmetic	Cosmetic	Cosmetic	Cosmetic
Lipstick	Cosmetic	Cosmetic	Cosmetic	Cosmetic
Sunscreen	Cosmetic (subject to positive list)	Over-the-counter (OTC) drug	Cosmetic	Non-prescription drug
Anti-acne lotion	Medicinal product	OTC drug	Quasi-drug	Non-prescription drug
Anti-caries toothpaste	Cosmetic	OTC drug	Quasi-drug	Non-prescription drug
Anti-perspirant	Cosmetic	OTC drug	Quasi-drug	Non-prescription drug
Hair dye	Cosmetic	Cosmetic	Quasi-drug	Cosmetic

[1] The types of products referred to in this table are 'normal' products, i.e. products not having the composition or claims more appropriate for another product category. For example, in the case of lipstick, the product considered is a lipstick having no additional SPF function.

The regulation of products categorised as **cosmetics** is broadly similar between the major markets, including:

- full responsibility of the manufacturer for the safety of products;
- in-market surveillance by regulatory authorities;
- no requirements for pre-market registration;
- no restrictions on sales channels;
- Good Manufacturing Practice guidelines (non-legislative, and which may differ between countries) specifically developed for cosmetics; and
- regulatory focus on product safety (rather than efficacy).

There are differences in the detail of regulations, including the number and type of ingredients included within positive and negative lists, labelling requirements (with differences remaining in the use of INCI terms) and the nature of safety and efficacy information to be maintained by manufacturers.

By contrast, regulation of products categorised as **drugs** generally requires:

- pre-market registration and approval of products, or adherence to specified ingredients and manufacturing methods;
- mandatory adoption of drugs (rather than cosmetics) Good Manufacturing Practice;
- labelling in line with drugs (rather than cosmetics) requirements;
- restrictions on sales channels in certain countries; and
- regulatory focus on product safety and efficacy.

Regulations applying to drugs are not specifically adapted to the needs of cosmetics, as they have been developed for products with therapeutic properties. They can be more time-consuming and expensive for manufacturers to meet, and less flexible, but there is no evidence that drug regulations lead to greater safety of non-therapeutic products than cosmetics regulations. In practice, similar key safety tests are carried out on similar products, regardless of their categorisation. Under drug regulations, though, the form of information to be provided and, in some cases, the way tests are carried out, can be less focused on the needs of cosmetics.

Adoption of Regulatory Models by Other Countries

Although the major markets account for a large proportion of total world cosmetics sales, third countries are of significant and growing importance. Outside Europe, a number of countries and/or regions have used the EU model in drafting their own cosmetic regulations. These include the ASEAN, Mercosur and the Comunidad Andina (Andean Pact) regions. Other countries have reproduced certain features of the EU model, including China, Algeria, India, Israel, Morocco and Saudi Arabia. The features of the EU model that have been adopted in other countries/regions include:

- the **broad definition** of a cosmetic: relatively few countries (most importantly Korea, with functional cosmetics) have adopted categories similar to the Japanese quasi-drug category or have classified products as OTC drugs, as in the USA and Canada;

- regulation of substances based on **negative and positive lists**. Around 30 countries are thought to have adopted the EU lists (though often with some modifications); and

- **manufacturer responsibility** for the product safety with in-market surveillance systems to monitor compliance.

However, emerging markets often maintain systems for registration of manufacturing sites, more similar to requirements for drugs and quasi-drugs in the major markets, and sometimes for products. This is thought to be related to a lack of resources and expertise for in-market surveillance. Emerging markets may also retain customised labelling requirements.

III. Consequences of Differences in Regulatory Frameworks

Barriers to Trade

Differences in regulatory frameworks for cosmetics have implications for stakeholders because of the global nature of the cosmetics industry. Global trade in cosmetics is significant, and international companies account for over 80% of cosmetics production in the EU, for example. Companies often seek economies of scale by producing international products that can be sold in all markets. Differences in regulatory frameworks can hinder this process, resulting in:

- reduced ranges of products available for consumers;
- enforcement problems for regulators, because products imported into their country may not comply with local regulatory frameworks; and
- increased costs, marketing delays and loss of sales for manufacturers and importers.

Some of the most significant impacts arise from the requirements applicable to products categorised as over-the-counter (OTC), non-prescription or quasi-drugs. Pre-market registration of a new OTC or quasi-drug product can incur significant additional costs and take a considerable period of time. Constraints on making changes to the ingredients used, and the difficulty of obtaining approval for new ingredients, limit the extent to which a single product can be sold across markets.

For example, sun products and products with a Sun Protection Factor (SPF) are categorised as cosmetics (subject to positive lists of ingredients) in the EU and Japan, as OTC or non-prescription drugs in the USA, Canada and (if they have an SPF over 4) in Australia, and as functional cosmetics in Korea. In each market, UV filters have to be approved on the basis of safety before they can be used. However, the nature and efficiency of approval processes varies; file preparation and approval takes a few months in Australia, 3-4 years in the EU and 6-8 years in the USA. There are also differences in labelling requirements and permitted claims and different methods for assessing SPF. The result is that only nine UV filters, all older ones, are permitted in all markets. This compares with a list of 26 UV filters approved for use in the EU after stringent safety testing. In the USA, only two new UV filters have been accepted for use since 1978; certain filters have been refused approval in the past, despite US assessments indicating that they are safe, because they have not been used previously in the USA. These differences act as a barrier to trade, as products must be tailor-made for specific markets on the basis of the regulatory process, rather than safety concerns or consumer preference.

Constraints on Innovation

The market for cosmetics in the EU grew by an average of 5% per year between 1998 and 2002. Growth in the USA over the same period was slightly lower, whilst the market in Japan remained flat or even contracted. Product innovation is a major driver for growth in the EU; several thousand new or improved products are placed on the market each year with major companies, on average, reformulating or replacing around 25% of their cosmetic products annually.

Innovations in cosmetics can be divided into three broad types, affected in different ways by the diverging regulatory frameworks at international level:

- **innovations in delivery mechanisms**: these have been a major source of market growth for the cosmetics sector in recent years and include, for example, shaving foams in gel form and cosmetic wipes, as well as the use of nanotechnology to deliver UV filters and vitamin E in anti-ageing creams into the first layer of the skin. Differences in regulatory frameworks are not currently a significant issue for this type of innovation, as the same requirements generally apply to the product however it is delivered;

- **innovations in ingredients and product composition**: differences in permitted ingredients mean that new formulations based on existing ingredients cannot be launched universally. Where a product is categorised as a drug or quasi-drug, ingredient changes cannot be made without prior approval, leading to delays and additional costs. Approval for new ingredients can also take considerably longer for products categorised as drugs or quasi-drugs; and

- **innovations in marketing and presentation of products**: these emphasise the contribution of cosmetics to a feeling of 'well-being' as well as an improved appearance. By contrast, the definitions of cosmetics in existing regulatory frameworks reflect the view that the external parts of the body to which cosmetics are applied are a separate external envelope, which are not linked to internal parts of the body or with the mind. Where the promotion of well-being is presented as the main purpose of a product, this could lead to uncertainty about its categorisation and act as a barrier to innovation.

Stakeholders contacted for the study, both inside and outside the EU, indicated that the current EU model has enabled innovation, rather than acting as a barrier. This is particularly the case when compared with regulatory frameworks in the USA and (at least until deregulation in 2001) to Japan. A number of recently introduced changes to the EU regulatory framework, however, could have the potential to act as a barrier to innovation in future. These include, in particular, the testing and marketing bans introduced by the 7th Amendment and additional requirements imposed by REACH.

IV. Conclusions and Recommendations

Conclusions

The general conclusions of the study are that:

- although the extent of alignment between regulatory frameworks in different countries is increasing, significant divergences remain. The most significant of these arise from the categorisation of products as either cosmetics, drugs, or quasi-drugs, which results in different regulatory procedures;

- the current divergence of regulatory frameworks can act as a barrier to trade and a constraint on innovation;

- further alignment of regulatory frameworks could contribute to the removal of barriers to trade and encourage innovation, whilst ensuring a high level of protection of consumer safety;

- the EU Cosmetics Directive, which combines a wide definition of cosmetics with clear and comprehensive requirements on safety testing, ingredients and labelling, provides a good basis for achieving further alignment, demonstrated by the number of countries and regions already modelling their approach upon it; and

- the alternative model, with a narrow definition of cosmetics subject to limited controls, is unlikely to be acceptable to regulators outside the USA and Canada as providing adequate protection for the consumer, particularly in the emerging markets where the effective in-market surveillance required to make this model work may not be present. The fact that many products categorised as cosmetics elsewhere are regulated as drugs under this model acts as a constraint on innovation without enhancing consumer safety.

There are a number of barriers to further alignment of regulatory frameworks. These include the fact that current frameworks have developed over a considerable period of time, reflecting cultural differences between markets as well as legislative traditions. Cosmetics regulations may also be linked to a wide range of other legislation, so that significant changes would have wide ramifications. There are also national differences in views on a number of key issues, such as the need for and acceptability of animal testing, that may be difficult to resolve. Nevertheless, stakeholders expressed considerable support for moves to further align regulatory frameworks for cosmetics and identified a number of positive actions that could be taken.

Recommendations

A number of measures could be adopted to enhance the alignment of cosmetics regulatory frameworks, to encourage innovation and enhance market growth:

- **a higher degree of convergence in the definition of cosmetics, preferably** in line with the definition in the EU Cosmetics Directive, would significantly

increase alignment of regulatory frameworks. Where this is not acceptable to regulators, simplified and transparent procedures for registration of OTC/quasi-drugs would help to reduce barriers to trade;

- **explicit recognition of producer responsibility for product safety**, **based on** effective in-market surveillance **as a prerequisite for a high level of consumer safety.** By reducing the need for pre-market approval by regulatory authorities, this would contribute to the reduction of barriers to trade without compromising consumer safety;

- **common positive lists of ingredients** would significantly reduce barriers to trade and constraints on innovation. If this is not possible, ingredients included in the positive lists in one of the main markets, particularly newly-accepted ingredients for which full data files are available, should be readily recognised and accepted by the competent authorities of the other major markets. Greater transparency in the process for identifying ingredients of concern, assessing them and decision-making would help to reduce barriers related to prohibition and restriction of ingredients;

- **common guidelines, e.g. for approaches to safety testing, in particular regarding alternatives to animal testing**. Ideally, there should be mutual recognition of safety assessments between at least the major markets; this has been achieved successfully for drugs regulation. Progress towards this goal could be made through the development of common international guidelines, for example on stability and efficacy testing; and

- **greater alignment in labelling and packaging rules**. There appears to be a growing consensus on the use of INCI terms for ingredient labelling, but more could be done to address the remaining differences. The proposed ISO rules on labelling, which appear to be close to agreement, could possibly provide the basis for further harmonisation.

Actions for Different Stakeholders

A range of stakeholders can contribute to achieving these recommendations, including the European Commission, national authorities, international organisations and industry:

- **All stakeholders** should participate in the different fora bringing them together. Close co-operation between stakeholders can assist in identifying practicable solutions that strike a balance between public health/consumer protection and business interests, thus ensuring the long-term economic viability of the industry.

- **European institutions** should take specific account of the international impact that new EU legislation will have, at the stage when proposals are being made, to ensure that changes do not present a barrier to harmonisation. They could also take an increased role at international level, for example through continuing to

provide funds for capacity-building measures on technical issues to third countries, as has been done with ASEAN, exploring the feasibility of developing a system of mutual recognition of evaluation and assessment criteria for ingredients as a step towards mutual acceptance and further dialogue on regulatory issues with authorities in emerging markets;

- **Regulatory authorities** can contribute to alignment of regulatory frameworks through participating in initiatives such as the Cosmetics Harmonisation International Co-operation (CHIC) meetings between regulators in the major markets (including the European Commission), by developing bilateral agreements on matters such as GMP guidelines and inspection and, at a regional level, by effective implementation of harmonisation programmes such as the Mercosur and ASEAN initiatives;

- **International organisations** such as the OECD have a key role in the mutual acceptance of testing methods, particularly validation of alternative testing methods, whilst ISO activities in the development of international standards and guidelines on cosmetics, for example on cosmetics GMP, are also very important; and

- **Industry** initiatives such as the three-yearly Mutual Understanding Conferences, bringing together industry representatives and regulators from around the world, as well as ongoing dialogue between industry representatives from the major markets, are already proving valuable in enhancing industry understanding of regulatory frameworks. The industry also plays a key role through the development and implementation of international guidelines, such as the SPF testing methodology developed by industry associations in the EU, Japan and South Africa and the IFRA codex of fragrances. Working towards international guidelines on other aspects of cosmetics regulation could provide an efficient and effective way to promote further alignment of regulatory practices, without necessarily requiring major legislative changes.

PART II

PRINCIPLES AND DETAILS OF DIFFERENT REGULATORY FRAMEWORKS FOR COSMETIC PRODUCTS INCLUDING SO-CALLED BORDERLINE PRODUCTS

1. INTRODUCTION

1.1 Regulatory Frameworks for Cosmetics Products

The manufacture, distribution and sale of cosmetics is a global industry within which the EU is a major player. The EU market for cosmetics is larger than the US market and twice the size of the Japanese market. Although data are not comprehensive, the value of output of the EU cosmetics industry is estimated at around €35 billion in 2001. This is equivalent to 0.4% of total EU GDP and 2-3% of manufacturing value-added. The industry employs over 150,000 Europeans directly. This is equivalent to 0.6% of total manufacturing employment and nearly 9% of total chemical industry employment. A further 350,000 jobs in retail, distribution and transport depend upon the cosmetics industry.

The cosmetics sector is characterised by global brands, with most multinational companies selling a high proportion of their products across all key markets. Most cosmetics products have lifetimes below five years, with up to 40% of products being reformulated or replaced each year. The exception is fine fragrances, some of which have remained on the market for 100 years.

Cosmetic products are subject to regulatory controls in all markets, in order to ensure the safety of products and avoid adverse impacts on the health of users. In the EU, the regulatory framework is provided by the Cosmetics Directive and its subsequent amendments. However, regulatory frameworks between the different markets differ significantly and the regulations for the major markets are far from being harmonised. This has the potential for impacts on the competitiveness and economic viability of the industry. The inability to sell similar products across all markets, or the requirement to change test methods, formulations, packaging and advertising, could increase costs for the sector. Delays and high costs associated with the introduction of new ingredients and products can also reduce the potential for market growth.

This Part of the Report describes the regulatory frameworks in the major cosmetics markets (the EU, USA, Canada and Japan), analyses the similarities and differences of these frameworks and assesses the implications for stakeholders.

1.2 Borderline Products

Differences in regulatory frameworks can be particularly significant for so-called 'borderline products'. The term 'borderline products' refers to those products that at first sight might be difficult to classify into one or another product category, either in the same country or in different countries. Broadly speaking, there are two types of borderline products:

- products defined as cosmetics within a *particular country or region* but which have certain properties, effects and/or claims associated with products defined by other legislation *for the same country/region*. In this case, the borderline is between two

pieces of legislation, or more specifically, between two product categories defined under two different pieces of legislation and this situation is present in every regulatory system; and

- products which are categorised as cosmetics in some markets/regions but under other categories, such as drugs, quasi-drugs or biocides in others. Such products are thus subject to a quite different regulatory regime from one country/region to another. These could range from requirements for pre-market approval to limits on the use of certain ingredients.

Table 1.1 illustrates some examples of the different categorisation of products under different regulatory regimes. It is important to note that the classification of products depends on the composition of the product (for example, the presence of certain active ingredients) and the claims made on the product. Therefore, the position in practice is more complex than a single table can illustrate.
See previous comments

Table 1.1: Illustrative Examples of Product Categorisation in Different Markets

Product Type[1]	Market			
	EU	USA	Japan	Canada
Soap for hands	Cosmetic	Cosmetic	Cosmetic	Cosmetic
Lipstick	Cosmetic	Cosmetic	Cosmetic	Cosmetic
Sunscreen	Cosmetic (subject to positive list)	Over-the-counter (OTC drug)	Cosmetic	Non-prescription drug
Anti-acne lotion	Medicinal product	OTC drug	Quasi-drug	Non-prescription drug
Anti-caries toothpaste	Cosmetic	OTC drug	Quasi-drug	Non-prescription drug
Anti-perspirant	Cosmetic	OTC drug	Quasi-drug	Non-prescription drug
Hair dye	Cosmetic	Cosmetic	Quasi-drug	Cosmetic

[1] The type of products referred to in this table are normal products, i.e. products not having the composition or claims more appropriate for another product category. For example, in the case of lipstick, the product considered is a lipstick having no extra SPF function.

1.3 Organisation of the Report

The remaining sections of this Report are organised as follows:

- Section 2 describes the regulatory frameworks in the European Union (Section 2.1), the United States of America (Section 2.2), Japan (Section 2.3) and Canada (Section 2.4);

- Section 3 provides a comparative analysis of the regulatory framework in these major markets;

- Section 4 discusses the implications of differences in regulatory frameworks and presents a number of illustrative case studies;

- Section 5 highlights the significance of third party markets for cosmetics;
- Section 6 discusses the regulatory frameworks in China (Section 6.1), Mercosur countries (Section 6.2), ASEAN region (Section 6.3) and other third countries (Section 6.4);
- Section 7 provides an overview of the significance of new developments and trends;
- Section 8 analyses the impacts of current regulatory frameworks on innovation within the cosmetics industry; and
- Section 9 discusses the potential for further alignment of the regulatory frameworks.

2. THE REGULATORY FRAMEWORKS IN THE MAJOR MARKETS

2.1 The Regulatory Framework in the European Union

2.1.1 Definition of Cosmetics and Borderlines with Other Regulations

Introduction

The category 'cosmetic product', as defined in the EU Cosmetics Directive (76/768/EEC) has borders with a range of product categories, including medicinal products, biocides and medical devices. For example, skin creams designed to moisturise the skin and protect it from UV radiation are defined as cosmetics, whilst anti-acne creams are defined as medicinal products.

Unlike the situation in the USA (see Section 2.2), case law of the European Court of Justice clearly states that a product cannot fall within the definition of two product categories at the same time. Case law[1] also specifies that, in classifying a product within one category or another, account must be taken not only of the definitions within the relevant legislation but also of the characteristics of the products themselves. The competent authorities and legal systems within Member States have some discretion in considering the classification of products on a case-by-case basis. This has resulted in some differences in the treatment of products between Member States, but in general the classifications appear similar for most products.

The Council of Europe (CoE, 2001) has also prepared an inventory of the situation in various Member States with regard to the classification of individual products. Guidance is provided at national level, for example, the UK Medicine and Healthcare Products Agency's regularly updated guidelines set out criteria to help competent authorities and legal authorities to determine the appropriate category for a product.

Definition of Cosmetic Products

The EU Cosmetics Directive defines a cosmetic product as:

> *'any substance or preparation intended to be placed 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 exclusively or mainly to cleaning them, perfuming them, changing their appearance and or/correcting body odours and/or protecting them or keeping them in good condition'.*

The definition is thus based on the parts of the body to which products are applied and the purposes for which they are applied. Annex 1 to the Directive provides an indicative list by category of products to be considered as cosmetic products in Member States. These are shown in Table 2.1. The list in Annex 1 is, however, not exhaustive, so that

[1] For example, cases C-290/90, C112/89, and C-369/88.

other products can also fall under the definition of cosmetic products. The recitals of the Directive provide explicit guidance on the borderline between cosmetic and medicinal products.

Table 2.1: EU Cosmetics Directive - Illustrative List by Category of Cosmetic Products
• Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.)
• Face masks (with the exception of chemical peeling products)
• Tinted bases (liquids, pastes, powders)
• Make-up powders, after-bath powders, hygienic powders, 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, creams, oils), hairdressing products (lotions, lacquers, brilliantines))
• Shaving products (creams, foams, lotions, etc.)
• Products for making-up and removing make-up from the face
• Products intended for application to the lips
• Products for care of the teeth and of the mouth
• Products for nail care and make-up
• Products for external intimate hygiene
• Sunbathing products
• Products for tanning without sun
• Skin-whitening products
• Anti-wrinkle products

Definition of Medicinal Products

Directive 2001/83/EC[2] defines a medicinal product as:

> *'(a) Any substance or combination of substances presented for treating or preventing disease in human beings or animals.*
> *(b) Any substance or combination of substances which may be <u>used in or</u> administered to human beings or animals with a view to making a medicinal diagnosis or to restoring, correcting or modifying physiological functions <u>by exerting a pharmacological, immunological or metabolic action</u>'.*

Under this definition, a product can be defined as a medicinal product according to either its composition or presentation. Under definition (a) a product could be considered to be a medicinal product if it is presented for treating and preventing disease, even if it does not in fact have such an effect. In practice, though, case law (see Case C-112/89) has stated that only products that 'significantly affect the metabolism' should be categorised as medicinal products. Similarly, the fact that a product is presented simply as helping to protect against certain diseases, for example a toothpaste that claims to help protect against dental caries, does not qualify it as a medicinal product in most Member States.

[2] Directive 2001/83/EC has been recently amended by Directive 2004/27/EEC, resulting in a change in the definition. The amendments are underlined in the text.

Definition of Biocidal Products

Biocidal products are defined in Directive 98/8/EC as:

> *'Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the actions of, or otherwise exert a controlling influence on any harmful organism, by chemical or biological means'.*

The Biocidal Products Directive covers a wide range of products across four main product categories: general biocidal products and disinfectants, preservatives, pest control and other biocidal products. The Directive is not intended to apply to products covered by other Community legislation (including the Cosmetics Directive). Cosmetics with secondary biocidal claims (for example, a sunscreen containing an insect repellent) are also not covered by the Directive, providing the primary function of the product is cosmetic. However, guidance on the borderline between the Biocides Directive and the Cosmetics Directive has not yet been finalised.

2.1.2 Regulation of Cosmetics in the EU

Introduction

The EU Cosmetics Directive (76/768/EEC) was adopted on 27 July 1976. The Directive aims to guarantee the safety of cosmetic products for human use while encouraging commercial exchange and eliminating barriers to trade (EC, 1999). The EU Cosmetics Directive has to date undergone seven amendments and 31 adaptations[3] to technical progress.

The European Commission has overall responsibility for cosmetics legislation within the EU. Each Member State designates a competent authority that enforces the legislation.

Pre-market Requirements

There is currently no requirement under the EU Cosmetics Directive for registration of cosmetic manufacturers or importers, or for pre-market approval for cosmetic products imported into or manufactured within the EU.

Article 7 of the Directive requires a simple notification to the relevant Member State authority of the place of manufacture or of initial importation into the EU of cosmetic products. Some Member States (for example Belgium and Spain) also request notification of products prior to marketing.

[3] Amendments modify the Articles or text of the Directive while Adaptations introduce changes in the Annexes.

Controls Over Ingredients

Restrictions and prohibitions on ingredients that can be used in cosmetics are included in various lists under the EU Cosmetics Directive:

- Annex II lists over 400 substances that are prohibited for use in the composition of cosmetic products (negative list). This number will increase significantly once the provisions of the 7th Amendment regarding CMRs is implemented[4];
- Annex III lists over 90 substances which cosmetic products may only contain subject to the restrictions and conditions laid down (restricted list);
- Annex IV is a positive list of over 150 cosmetic colourants permitted for use in cosmetic products;
- Annex VI is a positive list of over 50 preservatives that are permitted in cosmetic products; and
- Annex VII is a positive list of over 20 ultraviolet (UV) filters that are permitted in cosmetic products.

Where substances are subject to a positive list, the inclusion of a new substance on a positive list is preceded by a scientific evaluation of the risk of the substance by the Scientific Committee of Cosmetics and Non-Food Products Intended for Consumers (SCCNFP).

The SCCNFP[5] is an independent group of qualified scientists with significant experience in risk assessment, appointed by the European Commission. The SCCNFP also reviews the positive and prohibited/restricted lists in response to technical progress and/or concerns about the impacts of particular ingredients on safety. However, the final decision on addition (or removal) of substances from the lists is taken by the Commission and the Member States.

Labelling and Warnings

General labelling requirements are listed in Article 6 of the Directive. Information that must appear on the cosmetic product includes:

- the name and address of the manufacturer or person placing the product on the market;
- the batch number;
- nominal net content;
- the function of the product;
- the date of minimum durability (if up to 30 months) or period after opening within which the product can be used safely;

---

4 This prohibits the use of substances with category 1 and 2 carcinogenic, mutagenic or reprotoxic (CMR) properties, with the potential for risk assessment based exemption for Category 3 CMRs. (See also Section 7 of this Report).

5 The SCCNFP was formerly known as the Scientific Committee on Cosmetology and will be replaced in future by the Scientific Committee on Consumer Products (SCCP). The SCCP will consist of 19 members drawn from all of the EU Member States (including the new Member States).

- a list of ingredients in descending order (including any of a list of 26 fragrance allergens);
- usage precautions; and
- warnings for regulated ingredients.

The address where the product safety information is kept within the EU must also be identified.

Ingredient listing is required only on the outer packages of cosmetic products, using the International Nomenclature of Cosmetics Ingredients (INCI) which aims to establish a single name for each ingredient used in cosmetic composition. Warning statements are required for products containing certain ingredients listed in the Annexes of the Directive. These warnings must be on the outer and inner packages and are required by all Member States in their respective national languages. Special warnings exist for aerosols as set out in Council Directive 94/1/EC.

Testing and Safety

The safety of cosmetic products placed on the EU market is the responsibility of the person who places the product on the market, assured through in-market surveillance. In-market surveillance is the responsibility of competent authorities designated by each Member State. Producers or importers of cosmetics must ensure that cosmetic products do not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. The 7th Amendment to the Cosmetics Directive introduced a ban on animal testing of cosmetic products from 11 September 2004 and a ban on animal testing of ingredients not later than 11 March 2009 within the EU. It also introduced a ban on the marketing of cosmetic products tested on animals and products containing ingredients tested on animals, within the EU or elsewhere, not later than 11 March 2009. These measures are discussed further in Section 7.

The Directive does not require information on the safety of cosmetic products to be submitted to Member State competent authorities before a product is placed on the market. However, manufacturers/importers must retain information, accessible on request to Member State competent authorities at all times, on:

- the qualitative and quantitative composition of the product;
- physico-chemical or microbial specifications of ingredients and finished product;
- manufacturing method;
- safety assessment by qualified person;
- existing data on any undesirable effects; and
- proof for certain claims made.

Guidelines for safety testing have been prepared by the SCCNFP and the European Cosmetic, Toiletry and Perfumery Association (Colipa) has also published guidelines on the safety assessment of cosmetic products.

Although the EU Cosmetics Directive requires that cosmetic manufacturers adhere to good manufacturing practices (GMP), no definition of GMP is provided in the regulations. Voluntary GMP guidelines have been drawn up by Colipa, however, and the Commission is currently preparing EU guidelines.

2.1.3 Regulation of Other Product Categories in the EU

Medicinal Products

In the EU, products classified as medicinal products are regulated under the Medicinal Products Directive (2001/83/EC). This Directive has recently been amended (by Directive 2004/27/EC); new community procedures for authorisation and supervision of medical products have also been introduced by Regulation (EC) No. 726/2004.

The key differences between pharmaceuticals and cosmetics regulation are:

- pharmaceuticals are subject to a requirement for pre-market authorisation; they cannot be placed upon the market until authorisation has been granted;
- new pharmaceutical products will only be authorised if they meet the criteria of efficacy, quality and safety;
- applications for authorisation must contain a full technical dossier covering both safety and efficacy, including data on clinical trials;
- medicinal products must be manufactured in accordance with pharmaceutical GMP rules; and
- medicinal products are subject to limitations on advertising and distribution channels. Sales of medicinal products in the EU are subject to rules (which differ between Member States) limiting their sales to pharmacies. In some countries, though, for example the UK and Germany, certain medicinal products may be freely sold.

Biocidal Products

The Biocidal Products Directive (98/8/EC) controls the placing on the EU market of biocidal products. The Directive specifies that:

- only authorised biocidal products may be placed on the market;
- Member States are responsible for authorising biocidal products, with mutual recognition of authorisations (although mutual recognition procedures are not yet fully operational);
- only biocidal products containing active substances listed in Annex 1 and 1A of the Directive may be authorised; and
- active substances are to be evaluated and approved at EU level prior to a specified date. If approval has not been obtained by this date, products containing these active substances must not be placed on the market.

A comprehensive assessment of active substances is to be carried out before they are included in Annex 1 or 1A, based on their effectiveness and the absence of unacceptable effects on target organisms, human or animal health and the environment. Data to provide the basis for assessment must be provided by manufacturers or importers. The requirement applies to both new and existing active substances. Existing substances are subject to a 10 year review programme; they may remain on the market until an EU decision is taken on their inclusion in Annex 1 or 1A.

2.2 The Regulatory Framework in the United States of America

2.2.1 Definition of Cosmetics and Borderline with Other Regulations

Introduction

The Food, Drugs and Cosmetics Act (FD&C Act) defines two main categories of products:

- cosmetics; and
- drugs, including the specific sub-category of over-the-counter (OTC) drugs, which can be sold without prescription.

The definition of products as cosmetics or drugs depends on their intended use, which is established on the basis of claims made about the product, consumer perception (which may be established through a product's reputation, or the presence of ingredients with a well-known therapeutic use. According to the FD&C Act, a product may be regarded solely as a drug, solely as a cosmetic or (in contrast to the position in the EU) as both a drug and a cosmetic. The latter are products that meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses. For example:

- an anti-dandruff shampoo is a cosmetic because its claims indicate that the product's intended use is to clean the hair; but
- it is also considered to be a drug because it contains recognised anti-dandruff ingredients and its claims indicate that it is intended to be used to treat dandruff.

Products classified as both cosmetics and drugs must meet the requirements of regulations for both categories of products.

Definition of Cosmetics

The FD&C Act defines cosmetics as:

> *'articles (other than soaps consisting of an alkali salt of a fatty acid and making no claims other than cleansing) intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance'.*

Product categories identified as cosmetics under the FD&C Act are set out in Table 2.2.

Table 2.2: Examples of Cosmetic Product Categories Identified in the FD&C Act	
• Skin care • Fragrances • Eye make-up • Make-up other than eye • Manicure products • Bath oils and bubble baths • Mouthwashes	• Hair colouring preparations • Shampoos, permanent waves and other hair products • Deodorants • Shaving products • Baby products • Tanning products

Definition of Drugs

The FD&C Act defines drugs as:

> *'articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals'.*

Over-the-counter (OTC) drugs are drugs which can be purchased without a doctor's prescription. Examples of OTC drugs include anti-caries (fluoride-containing) toothpaste, moisturisers and make-up marketed with sun protection claims, anti-perspirants and anti-dandruff shampoos.

2.2.2 Regulation of Cosmetics in the USA

Introduction

The FD&C Act, which regulates cosmetics in the USA, was introduced in 1938 as a revision of the then Food and Drugs Act 1906. Since then, it has remained largely unchanged except for the Colour Additive Amendments of 1960. The labelling, packaging and advertisement of cosmetic products are regulated under the Fair Packaging and Labelling Act (FPLA) of 1967.

The Food and Drug Administration (FDA) has overall responsibility for enforcement of the regulations concerning cosmetics and pharmaceuticals. Within the FDA, the Office of Colours and Cosmetics within the Centre for Food Safety and Applied Nutrition (CFSAN) regulates cosmetic products.

Pre-market Requirements

In the USA, cosmetic products are not subject to pre-market approval and companies are not required to submit information on their products or to register cosmetic manufacturing establishments.

Manufacturers or distributors of cosmetics may, however, submit information on their products voluntarily through the Food and Drug Administration's (FDA) Voluntary

Cosmetic Registration Program (VCRP). If a cosmetic manufacturer files a product formulation with the VCRP, the FDA can advise the company if it is inadvertently using prohibited or restricted ingredients. Manufacturers can thus correct their formulations before attempting to market them in the USA, thereby avoiding the risk of having their products detained and/or denied entry into the USA because of a prohibited ingredient. Manufacturers may also report any adverse reactions.

Controls over Ingredients

No approval is required for the use of any new ingredient in a cosmetic (as long as the manufacturer takes responsibility for the safety of the final product). There are, however, a small number (15) of strictly regulated or prohibited ingredients. These include biothionol, hexachlorophene, mercury compounds (except under certain conditions as preservatives in eye cosmetics), vinyl chloride and zirconium salts in aerosol products, halogenated salicylanides, chloroform and methylene chloride.

In addition, all colour additives must be tested for safety and approved for their intended use by the FDA before they can be marketed in the USA. Each batch of a colour additive must be certified by the FDA.

Labelling and Warnings

Cosmetic labelling is regulated under the FD&C Act as well as the FPLA. According to the regulations, cosmetics produced or distributed for retail sale are required to carry an ingredient declaration on their outer package, while those not distributed for retail sale (e.g. preparations used by professionals on customers at their place of work) are exempt from these requirements. Country of origin labelling for imported cosmetic products is required by the US Department of Commerce.

Cosmetic ingredients must be listed by their established name (INCI names) as laid out in the Cosmetics, Toiletries and Fragrances Association (CTFA) International Cosmetic Ingredient Dictionary.

Testing and Safety

The safety of cosmetic products in the US is the responsibility of the manufacturer, supported by an in-market surveillance system. The FD&C Act prohibits the distribution of adulterated and misbranded cosmetics and requires that cosmetics must be safe for their intended use before being placed on the market. The Act authorises the FDA to conduct inspections of cosmetic firms (on the basis of complaints or suspicion of violation of law) without prior notice in order to assure compliance with the regulations.

Although there is no statutory process for reviewing the safety of cosmetics ingredients, a voluntary process, the Cosmetics Ingredients Review (CIR), was established in 1976. The CIR is funded by the CTFA, with support from the FDA and the Consumer Federation of America. It reviews and assesses the safety of ingredients used in cosmetics and publishes the results in the scientific literature. Ingredients are selected for review on the basis of their potential biological activity, frequency of use in cosmetics

and extent of skin penetration, amongst other factors. The outputs of the CIR have no legal authority, however, and the FDA is not obliged to act on its findings.

There are no mandatory GMP requirements for cosmetics; companies follow GMP guidelines issued by the FDA as well as quality assurance guidelines published by the CTFA.

2.2.3 Regulation of Other Product Categories in the USA

Regulation of OTC Drugs

Within the FDA, the Centre for Drug Evaluation and Research (CDER) regulates OTC drugs. Products which are cosmetics as well as OTC drugs are regulated by both and CDER and CFSAN.

The regulatory requirements for OTC drugs are more extensive than the requirements applicable to cosmetics. OTC drug manufacturers are required to register their establishments within five days from the beginning of operations (and thereafter, re-register every year) by submitting a completed Registration of Drug Establishment Form. OTC drug products must also be registered within five days after the beginning of operations and the list of all manufactured drugs must be updated twice a year.

The active ingredients approved for use in OTC drugs are specified in relevant OTC drug monographs. Any new active ingredients have to undergo New Drug Approval (see Section 3.3.2). The introduction of Time and Extent Applications (TEA) in 2001 was designed to ease this requirement; ingredients used in products marketed for at least five years outside the USA can be introduced more easily into OTC products subject to monographs. As yet, though, no ingredients have been approved under TEA.

OTC drugs monographs also set out restrictions, testing and labelling requirements. Labels must list the active ingredients first, according to their US Pharmacopoeia names, followed by the inactive ingredients in descending order of predominance. The active ingredient of such products must also be listed on the inner container, along with any relevant warnings prescribed in the OTC monographs according to product category. Manufacturers of OTC products must also follow GMP as laid out in the regulations.

The sale of OTC drugs is, however, not restricted to pharmacies or specialised stores.

Regulation of Other Drugs

Certain products categorised as cosmetics in the EU are categorised as new drugs rather than OTC drugs. A new drug is defined as a drug which has not yet been generally recognised by experts to be safe and effective under the conditions of intended use, or which has not been used to a material extent or for a material time. The safety and effectiveness of such products has to be proved to the regulatory agency through the New Drug Application (NDA) process before they can be marketed. This process is similar to the registration process for medicinal products in the EU, requiring the submission of detailed information on safety and efficacy.

2.3. The Regulatory Framework in Japan

2.3.1 Definition of Cosmetics and Borderlines with Other Regulations

Introduction

The Pharmaceuticals Affairs Law (PAL) defines three relevant categories of product:

- cosmetics;
- quasi-drugs; and
- drugs.

The Act specifies that, as in the EU, products can only fall within the definition of one category and thus have to comply with the requirements specific to this category. However, the PAL also sets out some general provisions that affect all three categories.

Definition of Cosmetics

Under PAL, the term cosmetic applies to:

> '*products (other than quasi-drugs) designated to be applied to the body by rubbing, spraying or other similar applications with the aim of cleansing, beautifying or making it more attractive or modifying its appearance and of maintaining the skin and hair in good condition, to the extent that the action of the product on the human body remains moderate*'.

Product categories identified as cosmetics under the Japanese PAL are set out in Table 2.3.

Table 2.3: Examples of Cosmetic Product Categories Identified in the Japanese PAL

• Cleansing Products	• Nails Products
• Hair Care Products	• Eyeliners
• Treatment Products	• Products for the Lips
• Make-up Products	• Oral Products (Mouth Rinse, no disinfection properties)
• Perfumes	
• Sun-care Products	• Bath Products

Definition of Quasi-drugs

Under the PAL, quasi-drugs are defined as products with a fixed purpose of use, that have a mild effect on the body but are not intended for use in the diagnosis, cure or prevention of disease or to affect the structure or function of the body. The purposes of use of quasi-drugs are specified in the PAL as:

- prevention of nausea or other discomfort, foul breath or body odour;
- prevention of prickly heat, sores and the like;
- prevention of hair loss, to promote hair growth, or for hair removal; and

- eradication of or repellence of rats, flies, mosquitoes, fleas, etc. for the health of man or other animals.

They may also be:

- cotton product intended for sanitary purposes; or
- specified products with a mild action on the human body. These products are listed in Table 2.4.

Table 2.4: Products Designated as Quasi-drugs under the PAL

• Mouth wash products (for disinfection of the mouth) • Deodorants • Talc powder (with active ingredient) • Hair-growth products • Depilatories • Hair dyes (oxidative) • Bath preparations (with active ingredients) • Permanent wave products	• Medicated cosmetics (including anti-dandruff shampoos and rinses, anti-acne, anti-chapping and anti-frostbite lotions, creams and packs, whitening and anti-bacterial products) • Insect repellents • Medicated toothpastes • Cotton products intended for sanitary purposes • Anti-rodent products

Some claims that cannot be made for cosmetics are permitted to be made for quasi-drugs.

Definition of Drugs

Under the PAL, the term drug refers to:

- items recognised in the Japanese Pharmacopoeia;
- items (other than quasi-drugs) intended for use in the diagnosis, cure or prevention of disease in man and other animals, and which are not equipment or instruments (including dental materials and medical supplies and sanitary materials); and
- items (other than quasi-drugs and cosmetics) which are intended to affect the structure or function of the body of man or animals, and which are not equipment or instruments.

2.3.2 Regulation of Cosmetics in Japan

Introduction

The PAL was first adopted in 1943, with subsequent amendments in 1948, 1960 and 1979. In March 2000, the Japanese government published a three-year deregulation strategy, which led to the revision of the PAL as well as other legislation relevant to cosmetics. The deregulation process, implemented in 2001, involved the abolition of pre-market approval, the establishment of a prohibited and restricted ingredient list, the abolition of the designated ingredient list, and a new requirement for complete ingredient listing.

The Ministry of Health, Labour and Welfare (MHLW) has overall responsibility for enforcement of the regulations concerning cosmetics (as well as quasi-drugs and drugs).

Pre-market Requirements

Prior to the deregulation in 2001, pre-market approval was required for each cosmetic product to be marketed in Japan. This requirement has now been abolished and cosmetic products are no longer subject to pre-market approval.

Under the new regulations, companies are required only to provide notification of the product's brand name prior to manufacturing or importing. Manufacturers or importers of cosmetics are also expected to have a licence granted by the authorities upon inspection of the manufacturing site. This licence must be renewed every five years.

Controls over Ingredients

Until recently, Japan had a positive list system under which each ingredient used in a cosmetic formulation had to be pre-approved by MHLW. Since April 2001, however, Japan has adopted:

- a list of prohibited ingredients;
- a list of restricted ingredients;
- a positive list of UV filters; and
- a positive list of preservatives.

In addition, a positive list of colour additives from Ordinance 30 of 1966, still applies.

Cosmetics are not permitted to contain ingredients that are drug agents, except where these received approval for use in cosmetics before 31 March 2001, are contained in the Comprehensive Licensing Standards of Cosmetics by Category (CLS) or are used only as additives.

Full ingredient labelling must be provided for cosmetics, using INCI terms translated or transliterated into Japanese.

Labelling and Warnings

Cosmetics must be labelled with the product name, name and address of manufacturer or importer, content volume, product number or code and a list of ingredients.

Safety and Testing

Responsibility for cosmetic safety rests primarily with the manufacturer. Manufacturers or importers are required to check the safety of their products thoroughly before they are placed on the market and to maintain records of this. The health authorities may require a manufacturer to substantiate product safety.

There are no official or mandatory good manufacturing practice (GMP) in Japan, although the Japanese Cosmetic Industry Association (JCIA) has published voluntary technical guidelines for manufacturing and quality control.

2.3.3 Regulation of Other Product Categories in Japan

Regulation of Quasi-drugs

The quasi-drug category in the PAL (first recognised in regulations in 1916) was retained during the deregulation of cosmetics in 2001 and the changes to regulations on cosmetics do not apply to quasi-drugs. The regulatory requirements for quasi-drugs are more extensive than those applicable to cosmetics, and indeed are closer to the requirements for pharmaceuticals.

Quasi-drugs are subject to pre-market approval and licensing requirements. Registration of all ingredients used in product manufacture, as well as product safety data which specify the active ingredients, usage and dosage, indications or effects is also required. Full lists of approved quasi-drug ingredients are not published, although the MHLW has published lists of ingredients approved for use in certain categories, such as hair dyes, permanent waving agents and bath preparations. Full ingredient listing is not required for quasi-drugs; however, the MHLW has listed 138 ingredients that must be indicated on the label. There are also specific warning statements required by the regulations, which include warnings for hair dyes.

There are prescribed safety tests for quasi-drugs, although the data required for approval vary depending on whether the product is a new quasi-drug or a recognised previously approved quasi-drug[6]. For example, data on indications or effects are not required for recognised approved quasi-drugs and stability data may be omitted, depending on the conditions of the product.

Information on the composition, function of each ingredient, manufacturing process (permitted only in a licensed factory), product specifications, mode of use and recommendations, analytical methods for active ingredients, claims as approved, storage and durability must be made available when required.

Although the regulatory requirements for quasi-drugs are more rigorous than that for cosmetics (and more similar to that for drugs), quasi-drugs are treated like cosmetics at the distribution stage, and are not subject to limitations on distribution outlets.

A revision of the PAL, due to come into force in April 2005, transfers a number of products formerly regulated as drugs or medical devices to the category of quasi-drugs[7]. Manufacturers of these products will be required to follow GMP (although this requirement will not apply to products already categorised as quasi-drugs).

---

[6] In Japan, there is a two-year data exclusivity period for new cosmetic products; when the two years have elapsed, other Japanese manufacturers are allowed to use the information submitted during registration of the product.

[7] None of these products is categorised as a cosmetic in other major markets. They include, for example, antiseptics for external use, first aid adhesive tape, throat lozenges and vitamin drinks.

Regulation of Drugs

The Pharmaceutical Affairs Law establishes an approval and licensing system, as well as monitoring system at each stage of development, manufacture, import and distribution of drugs.

The evaluation and approval of pharmaceuticals in Japan involves three different organisations: the Ministry of Health, Labour and Welfare (MHLW), the Pharmaceuticals and Medical Devices Evaluation Center (PMSBEC) and the Organization for Pharmaceutical Safety and Research (OPSR)[8].

The approval procedure for a drug involves a written application which is forwarded to the MHLW through the PMSBEC. The PMSBEC forwards the application to the OPSR which reviews the documentation concerning the quality, efficacy and safety of the relevant drugs using established guidelines and standard methods for evaluating an application for drug approval. Where the application is successful, final approval is granted by the Ministry of Health, Labour and Welfare.

2.4 The Regulatory Framework in Canada

2.4.1 Definition of Cosmetics and Borderlines with Other Regulations

Introduction

Legislation in Canada identifies two main categories of products:

- cosmetics; and
- drugs (a specific sub-category of which is non-prescription (or OTC) drugs).

There is also a third category; natural health products. Unlike in the USA, a product can only be included within a single category.

The classification of a product as a drug rather than a cosmetic depends upon the claims made, as well as whether it uses ingredients or combinations of ingredients listed in Category IV monographs (which recognise ingredients as being safe and effective for non-prescription drugs).

Definition of Cosmetics

Cosmetics are defined as:

> *'any substance or mixture of substances, manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes'.*

[8] Under the proposed revisions to the PAL, it is expected that the PMSBEC and the OPSR will be merged with the Japanese Association for the Advancement of Medical Equipment.

This definition includes toothpaste (non-fluoride), skin lotions, cleansers, shampoos, conditioners, hair dyes, personal care products and soaps.

Definition of Drugs

The regulations define drugs as:

> '*any substance or mixture of substances manufactured, sold, or represented for use in (a) the diagnosis, treatment, mitigation or prevention of disease; (b) restoring, correcting or modifying organic functions in human beings or animals, or (c) disinfection in premises in which food is manufactured, prepared or kept*'.

Non-prescription drugs are drugs (as defined above) which can be purchased without a doctor's prescription. Products categorised as non-prescription drugs are regulated under Category IV monographs.

2.4.2 Regulation of Cosmetics in Canada

Introduction

Cosmetics in Canada are regulated under the Food and Drugs Act (FDA) which was adopted in the 1950s. The FDA is supplemented by the Cosmetic Regulations, which govern the composition, safety, labelling and advertising of cosmetics.

The Cosmetics Division of the Consumer Health Safety Bureau, part of Health Canada, has overall responsibility for enforcement of the regulations concerning cosmetics and pharmaceuticals.

Pre-market Requirements

There is no requirement for pre-market approval or registration for cosmetics. The Cosmetic Regulations, however, require every manufacturer to submit a completed Cosmetic Notification form to the competent authorities within 10 days from the day on which the product is placed on the market. The notification must include:

- the name and address of the person or entity identified on the product label;
- the name of the Canadian distributor;
- the product name;
- the purpose of the product; and
- a list of ingredients with the exact concentration or range.

The list of ingredients is compared to the Cosmetic Ingredients Hotlist, to ensure that the product does not contain prohibited or restricted ingredients (except in line with the prescribed restrictions) or ingredients that would classify the product as a drug. If there are problems with ingredients, the company can be required to reformulate the product, re-label it or register it as a drug. Cosmetic notification does not, however, constitute a

product evaluation or approval procedure, and does not indicate that the cosmetic meets the requirements of the Food and Drugs Act and Cosmetics Regulations.

Controls over Ingredients

Ingredient restrictions are contained in Sections 13, 14, 15 and 22 of the Cosmetic Regulations. Together, these form the 'Cosmetic Ingredient Hotlist' of almost 500 substances that are known to be active pharmaceuticals, to have adverse health effects or to be harmful as cosmetic ingredients. There are no positive lists of ingredients.

The Cosmetic Ingredient Hotlist is based broadly on the restricted lists of the EU Cosmetics Directive, although each substance was evaluated in detail by the authorities to determine whether there was any evidence to indicate that it should be subject to different controls in Canada.

Labelling and Warnings

The inner and outer label of a cosmetic product is required to show:

- the product identity in English and French;
- the name and address of the manufacturer or distributor; and
- a statement of net quantity and any necessary warnings or directions in English and French.

There are also special labelling requirements for hair dyes.

A proposed amendment to the Cosmetics Regulations will require mandatory ingredient listing on all cosmetic products sold in Canada. The aim of the amendment is to provide better protection for consumers and to enhance harmonisation with legislation in other markets, particularly the EU. The amendment is planned to be adopted by the end of 2004.

Safety and Testing

Responsibility for cosmetic safety rests primarily with the manufacturer. There are no requirements for specific testing to be carried out for cosmetics. Manufacturers may be required to submit safety data on any ingredient in response to concern arising from its structural relationship to other substances posing potential health risks, complaints or other sources. The Consumer Products Safety Bureau has the power to inspect any sites where cosmetics are manufactured, packaged or stored.

There are no specific GMP requirements for cosmetics manufacture; however, the Canadian Cosmetics, Toiletries, and Fragrances Association (CCTFA) has published voluntary industry GMP guidelines.

2.4.3 Regulation of Other Product Categories in Canada

Regulation of Non-prescription Drugs

Products for which a therapeutic claim is made, or that contain ingredients which are not permitted in cosmetics, are regulated under the Therapeutic Products Programme. Products making therapeutic claims must be registered as drugs and receive a drug identification number (DIN). Drug establishments must also be registered with Health Canada and require a Drug Establishment Licence.

Non-prescription drugs are subject to pre-market approval from the Therapeutic Products Programme, involving a review and registration process. For product registration, the manufacturer (or other responsible party) is required to certify that the product has been manufactured in compliance with Canadian GMP and the relevant Category IV monographs and that the product does not contain any prohibited substances. Changes in packaging or distributor require an amended registration, while changes in manufacturer require a new registration.

The Category IV monographs identify the ingredients recognised as safe and effective for use in non-prescription drugs and only these ingredients may be used. All active ingredients must be indicated on the product label.

There are mandatory GMP requirements for drugs and manufacturers and distributors are required to hold an establishment licence, as well as have a quality control department in Canada responsible for the sampling and testing of products prior to products being placed on the market. GMP certificates from countries with Mutual Recognition Agreements (MRA) and a Memorandum of Understanding with Canada are, however, accepted and this includes the EU.

Regulation of Natural Health Products

Products containing natural therapeutic ingredients are regulated by the Office of Natural Health Products under the Natural Health Products Regulations (which came into force on 1 January 2004). Certain products formerly categorised as cosmetics will in future be regulated under these regulations.

Natural Health Products (NHP) comprise products where the active ingredients are 'natural' rather than man-made. There appear to be some conflicting views over this definition. For instance, it was assumed that titanium dioxide (TiO_2) would be excluded, because it undergoes considerable processing before incorporation into products. It has been argued, however, that it should be included as its chemical composition remains unchanged. There are similar arguments over aluminium in anti-perspirants and fluoride.

Under the Natural Health Products Regulations, there are a number of requirements before the production, distribution and/or sale of a NHP, which include:

- each NHP product must be granted a Product Licence by the NHP Directorate before it can be sold. Evidence to support the efficacy and safety (testing) of the product

must be submitted for governmental approval before a Product Licence will be granted; and

- a site licence (granted by the NHP Directorate) will be required for manufacturers, packagers, labellers, and importers of NHPs. A prerequisite for the granting of this site licence is that good manufacturing practices are employed at the site.

3. COMPARATIVE ANALYSIS OF REGULATORY FRAMEWORKS IN MAJOR MARKETS

3.1 Main Sources of Differences in Regulatory Regimes

The previous sections in the Report demonstrate that the main differences in regulatory regimes between the major markets arise from the categorisation of products:

- regulation of products categorised as cosmetics shares certain similarities between the major markets, particularly producer responsibility for safety and the absence of pre-market approval requirements. However, there are significant differences in other aspects, for example in relation to positive and negative lists of ingredients;

- products categorised as drugs or quasi-drugs are regulated differently to cosmetics. They generally require pre-market approval and are subject to limitations on composition and manufacturing processes which reduce flexibility whilst not necessarily increasing safety. The range of cosmetic-type products categorised as drugs or quasi-drugs varies significantly between the major markets.

The difference between categorisation of products is partly for historic reasons. Basic legislation regulating cosmetics in the USA and Canada[9] has remained largely unchanged for a considerable period of time. The definitions of cosmetics were developed at a time when the range of cosmetic products and the ingredients used within them were limited. These product characteristics were enshrined in legal definitions which has meant that, as new products developed, they were classified as drugs.

By contrast, the EU Directive on cosmetics was introduced only in 1976 and has been subject to seven amendments and numerous adaptations due to technical progress, enabling definitions and controls to keep pace with product development. This has enabled new products to be included within the category of cosmetics.

Until 2001, legislation in Japan applied drug-like controls to all cosmetic products. However, a number of factors led to the deregulation of cosmetics in 2001. These included globalisation of the cosmetics market and the need to remove non-tariff barriers, the perceived high level of safety of cosmetic products and the growing administrative burden of dealing with an increasing number of new products. The deregulation process involved the abolition of pre-market approval, the establishment of a prohibited ingredient list similar to those in the EU, the abolition of the designated ingredient list, and a new requirement for complete ingredient listings to provide better consumer information. The quasi-drug category was retained, however.

[9] In Canada, the definition of cosmetics is being reviewed as part of the ongoing legislative renewal programme and the potential for changing the definition of cosmetics to one closer to the EU definition is being examined. However, this would have significant legal implications and, as such, it is not expected to happen quickly.

3.2 Similarities and Differences in Regulation of Cosmetics

3.2.1 Main Similarities in Cosmetics Regulation

Table 3.1 compares the main features of regulations for products categorised as cosmetics in the four main markets. Features common to cosmetics regulation in all four markets include:

- full responsibility of the manufacturer for the safety of products;
- in-market surveillance by regulatory authorities; and
- no restrictions on sales channels.

There are also broad similarities in labelling requirements and safety testing.

Manufacturer Responsibility

None of the four markets requires prior approval of products before they are placed on the market. Instead, manufacturers have full responsibility for ensuring that their products are safe, with in-market surveillance by competent authorities to ensure that regulatory requirements are properly met. However, Japan and Canada require notification of product names before they are placed on the market (and, in the case of Canada, notification of the ingredients). Some EU Member States also require notification of products.

Ingredient Labelling

Labelling of ingredients is required in the EU, USA and Japan, using INCI terms (translated in the case of Japan). Ingredient labelling is not yet mandatory in Canada, but an amendment introducing this requirement, using INCI terms, is expected before the end of 2004. All markets require quantity labelling using metric units; however, non-metric labelling is also mandatory in the USA and is permitted in Canada and in the EU (until 2009) as a supplement to metric labelling. All markets require the producer/importer identity to be labelled, although in Japan only a Japanese address is acceptable.

Safety Testing

No specific tests are required to determine product safety and efficacy, with manufacturers responsible for ensuring that adequate testing is undertaken to ensure the safety of their products. In the EU, testing guidelines are issued by the scientific advisory committee, the SCCNFP. In the USA and Japan, testing guidelines have been developed by industry.

Table 3.1: Comparison of Key Features of Cosmetic Regulations in the Major Markets				
Main Features	**EU**	**US**	**Japan**	**Canada**
General				
Manufacturer has full responsibility for safety of products	Yes	Yes	Yes	Yes
In-market control by authorities	Yes	Yes	Yes	Yes
Freedom to use any distribution channel	Yes	Yes	Yes	Yes
Pre-market Requirements				
Notification of products	Not required by Cosmetics Directive, although it may be requested by some EU Member States.	Voluntary notification	Mandatory notification of name of product	Mandatory notification of product name and function, plus quantitative or semi-quantitative ingredients list to be notified 10 days at the latest after placing the product on the market.
Initial notification of producer premises	Compulsory but requirements not harmonised.	Voluntary	Compulsory	Notification of producer and importer compulsory
Controls over Ingredients				
Positive and negative lists	Regulation of ingredients is based on lists of: - List of prohibited substances - List of restricted substances - Positive list - colouring agents - Positive list - preservatives - Positive list - UV filters	Short list of prohibited or restricted ingredients List of colorants included in FDCA Voluntary Cosmetic Ingredient Review recommendations are followed by industry	Regulation of ingredients is based on lists of: - List of prohibited substances - list of restricted substances - Positive list - colouring agents - Positive list - preservatives - Positive list - UV filters	Short list of prohibited substances. Hot List of around 500 ingredients either prohibited or restricted.
Scientific advisory committees	SCCNFP (committee of experts appointed by European Commission) advises Commission/Member States on safety of ingredients.	Cosmetic Ingredients Review (voluntary committee of experts organised by industry) advises on safety of ingredients.	Government officials and experts. The Cosmetics Advisory Committee is in charge of positive lists.	Government officials.

Table 3.1: Comparison of Key Features of Cosmetic Regulations in the Major Markets				
Main Features	**EU**	**US**	**Japan**	**Canada**
Notification of ingredients to poison centres	Most countries require frame formulations to be sent to poison centres, but as yet not harmonised at EU level.	No	No	No
Labelling Requirements				
INCI labelling of ingredients	Yes	Yes, but with some variations	Japanese translation of INCI terms required	Ingredient listing not yet required. Once proposal for mandatory listing becomes law, INCI terms will be adopted with some variations
Quantity labelling	Mandatory metric labelling. Non-metric labelling allowed as a supplementary until 2009.	Both metric and non-metric labelling mandatory	Mandatory (metric only)	Metric labelling mandatory. Non-metric labelling allowed as a supplementary.
Identity of producer/importer on the labels	Yes – name and address of person placing the product on the EU market.	Yes. Non-US address is accepted	Under present regulations, producer or importer in Japan must be identified. Under new regulations, (applicable from 2005), identity of person responsible for placing product on market will be mandatory.	Name and address of manufacturer or dealer. Non-Canadian address is accepted
Expiry date	Date of minimum durability if durability is $\leq$ 30 months. Period after opening if durability is > 30 months	No date required.	Expiration date if shelf-life < 3 years.	No date required.
Testing and safety				
Data on product safety and efficacy	Manufacturers must maintain a product information file (PIF) including a safety assessment by a qualified person, data on any undesirable effects and proof for certain claims made. PIF must be accessible to competent authorities on request at all times.	No equivalent to PIF - control is undertaken by FDA/FTC and other authorities. If the manufacturer does not have data to prove the safety of his product, the compulsory warning "*The safety of this product has not been determined*" must appear on the packaging.	No equivalent to PIF. Manufacturers must be able to prove safety/efficacy.	No equivalent to PIF but product safety must be proven upon request from the authorities.

Table 3.1: Comparison of Key Features of Cosmetic Regulations in the Major Markets				
Main Features	**EU**	**US**	**Japan**	**Canada**
Testing requirements	SCCNFP (committee of experts appointed by European Commission) publishes guidelines	No specific tests required. Industry guidelines on safety based on manufacturer responsibility.	No specific tests required. Industry has developed guidelines.	No specific tests required.
Animal testing ban	Animal testing and marketing ban introduced by 7th Amendment	No	No	No
GMP	Reference in Cosmetics Directive	Industry guidelines (voluntary)	Industry guidelines	Industry guidelines (voluntary)

3.2.2 Main Differences in Cosmetics Regulation

The main differences between regulatory regimes for cosmetics in the four main markets concern:

- controls over ingredients through positive and negative lists; and
- requirements for maintaining data on product safety and efficacy.

Additional differences will arise following implementation of the 7th Amendment to the EU Directive, which introduces animal testing and marketing bans. This issue is discussed further in Section 8 of this Report.

Negative and Positive Lists

The EU and Japan both maintain lists of prohibited and restricted substances, together with positive lists for colouring agents, preservatives and UV filters. The negative and restricted lists are updated regularly, on the advice of the scientific advisory committees or equivalent. Manufacturers wishing to use new ingredients subject to positive lists must obtain approval from the SCCNFP (EU) or the Cosmetics Advisory Committee (Japan), following the submission of safety data. However, the lists are not identical between the two markets and some ingredients that are prohibited or restricted in one market are permitted in the other. This issue is discussed further in Section 4 of this Report.

The USA and Canada do not have positive lists for cosmetic ingredients. This is partly because products containing ingredients subject to positive lists in the EU and Japan, for example UV filters, are regulated as OTC drugs in the USA and Canada. This means that they are required to undergo pre-market approval, unless they comply with a relevant OTC drugs monograph setting out permitted ingredients, manufacturing methods, etc. In addition, the USA requires all colour additives for cosmetics to be tested for safety and approved for their intended use.

The USA has only a short list of 15 prohibited or restricted ingredients for cosmetics; this is not subject to regular review. However, reviews of ingredient safety are also undertaken by the Cosmetics Industry Review (CIR), a committee of experts organised by the cosmetics industry, and its recommendations are generally followed by the industry. Although the CIR takes account of action on ingredient safety in the EU and Japan, it has reached different conclusions on the safety of particular ingredients in the past. Canada's Cosmetics Ingredients Hotlist, which indicates ingredients subject to restrictions or prohibition in cosmetics was broadly based on the restricted lists of the EU Cosmetics Directive. Each substance was reviewed in detail before being added to the Hotlist, however, giving the potential for differences from the EU lists.

Data on Product Safety and Efficacy

One of the key requirements of the EU Cosmetics Directive is that producers must maintain a file of information about their products, including the results of safety testing, data on any undesirable effects and proof for certain claims made. These files must be

made available to the regulatory authorities on request, and provide evidence that manufacturers have met their responsibility for product safety.

No such product information files are required under the regulations in the other major markets, although in Japan and Canada manufacturers must be able to prove the safety of the product (and, in Japan, its efficacy) on request. In the USA, manufacturers may place products on the market in the absence of data on safety but such products must carry a specific warning on the packaging.

3.3 Differences Arising from the Categorisation of Products as OTC, Non-prescription or Quasi-drugs

3.3.1 Introduction

The regulatory requirements for products that are categorised as OTC, non-prescription or quasi-drugs can be significantly different from those applicable to cosmetics. In particular, they can require:

- responsibility for safety shared between manufacturers and regulatory authorities, through requirements for pre-market registration and approval of individual products;
- mandatory registration of manufacturers' facilities;
- inflexibility in the introduction of new ingredients into products;
- limitations on claims that can be made;
- specific labelling requirements;
- specific testing procedures; and
- mandatory implementation of drug GMP, with the potential for inspection of manufacturers' facilities.

The impact of these differences is particularly significant where products categorised as cosmetics in one market are categorised as OTC, non-prescription or quasi-drugs in other markets. The major differences between the regulatory regimes for cosmetics and those for OTC, non-prescription and quasi-drugs are examined further below.

3.3.2 Main Differences in Regulation of OTC, Non-prescription and Quasi-drugs Compared to Cosmetics

Table 3.3 sets out the most significant and less significant differences in regulation arising from the categorisation of products as OTC, non-prescription and quasi-drugs in the USA, Japan and Canada respectively, based on the experience of manufacturers with how the regimes operate in practice.

Table 3.3: Major Differences in Regulatory Regimes for Products Under Other Categories in Major Markets			
	USA (OTC Drugs)	**Japan (Quasi-drugs)**	**Canada (Non-prescription Drugs)**
Most Significant Differences	• Active ingredients that have not been recognised as safe and effective for a designated use or condition by the FDA need to undergo a New Drug Application before they are marketed. • Manufacturer's premises may be inspected by FDA worldwide. • The combination of ingredients is regulated as well as individual ingredients. • Specifications of ingredients must comply with the corresponding ingredient monographs. • Claims that can be made and warnings are regulated in the individual OCT monographs according to product category. • Labelling requirements (Drug Facts Box) are cumbersome and not adapted to cosmetic OTC products. • Specific stability tests are required. • GMP for pharmaceutical products must be followed.	• Registration is required for new ingredients and those not covered by standards, registration fees are payable. • Manufacturer's premises must be approved. • The lists of accepted quasi-drug active ingredients are not published, except for oxidative hair dyes, perms, medicated bath products and toothpastes. • Specifications of ingredients and additives must correspond to those accepted by the Authorities. • There is a positive list of 55 claims allowed; any other claims are not permitted. • Specific stability tests are required. • GMP for pharmaceutical products is recommended.	• Drug Identification Number (DIN) is required. • Manufacturer's premises must be approved, even when abroad. • Products cannot be imported without a local contact • Mixture of ingredients is regulated. • Specifications of ingredients must comply with the corresponding ingredient monographs (US monographs when no Canadian monographs exist). • Claims that can be made and warnings are regulated in the individual OTC monographs according to product category. • Raw materials from plants only accepted as aromatic ingredients (otherwise regulated as Natural Health product). • Analysis of ingredients and preservatives is required as well as verification of physico-chemical and organoleptic specifications, resulting in specific labelling for Canada. • Labelling of an expiry date. • GMP for pharmaceutical products must be followed.
Less Significant Differences	• Registration of products is relatively simple when active ingredients in the product are identified in the relevant OTC drug monograph. • Requirement to substantiate stability and efficacy data is not too demanding, data must be available upon request.	• Registration of products with registered ingredients (and those covered by standards) is reasonable easy. • Responsibility for safety is shared between the Authorities and the manufacturer. • Labelling of ingredients is limited to ingredients designated by the Authorities (about 130) (potentially significant for consumers). • The quasi-drug category allows some claims to be made that cannot be made for cosmetic products. • No efficacy/safety data is necessary once the registration of an ingredient has been obtained. • Japanese drugs (and cosmetics) GMP developed by industry.	• Registration of new ingredients is reasonable easy. • Inspection of compliance with the Canadian pharmaceutical GMP is carried out for manufacturing plants in the EU by national European authorities in line with the European Pharmaceutical GMPs (via bilateral agreement).

Pre-market Registration

All three regulatory regimes require registration of products before they can be placed on the market. However, industry indicates that the process for registration is relatively simple, provided ingredients in the products are in line with the relevant monograph and meet the monograph specifications (USA, Canada) or are registered for that use (Japan). In Japan, though, lists of approved ingredients are only disclosed for hair dyes, permanent wave, medicated toothpaste and bath products, so it may be difficult for manufacturers to identify which ingredients are approved for which uses.

Where products contain new ingredients, or those not recognised or approved for that specific use, the ingredients must be registered. By contrast, regulatory regimes for cosmetics require prior registration only where ingredients are subject to positive lists (in the EU and Japan). However, as positive lists apply to the ingredients most likely to give rise to concern, the practical implication for product safety of the different approaches is minimal.

Manufacturers indicate that the procedure for registration of new ingredients in Canada is relatively straight forward (as is the procedure for approval of positive list substances under the EU Cosmetics Directive). In the USA, though, new ingredients not recognised as safe and effective by the FDA have to undergo a New Drug Application. This is a time-consuming procedure; the impacts of this requirement are discussed further in Section 4 of this Report. In Japan, new ingredients must also be registered and a fee is payable. In both the USA and Canada, the combination of ingredients as well as individual ingredients are regulated.

All three regimes also require approval of manufacturers' premises, even when located outside the country concerned. The US FDA has the right to inspect manufacturers' premises worldwide.

Claims and Labelling

All three markets limit the claims that can be made about products. In the USA and Canada, claims are regulated in the individual OTC monographs and no other claims are permitted, even if these could be substantiated. The monographs also specify warnings to be included in labels. In Japan, there is a positive list of 55 claims that are permitted, specified by product category; no other claims are allowed without prior approval. In each market, though, certain claims that are prohibited for cosmetics (or would result in their categorisation as OTC/non-prescription drugs in the USA or Canada) can be made for OTC, non-prescription or quasi-drugs.

Labelling requirements for OTC/non-prescription/quasi-drugs are also different from those for cosmetics. In Japan, full ingredient listing is not required for quasi-drugs. Only ingredients designated by the authorities (around 130 in total) have to be labelled. In Canada, the requirement to analyse ingredients and

preservatives as well as to verify physico-chemical and organoleptic specifications results in specific labelling for non-prescription drugs. In the USA, OTC drugs are required to be labelled with a 'drug facts box', with industry indicates is cumbersome and poorly adapted to cosmetic-type products.

Testing

Where ingredients have not already been approved for use in particular OTC, non-prescription or quasi-drugs, they must be tested to demonstrate their safety and efficacy. (This is similar to the requirement for cosmetics ingredients subject to positive lists in the EU and Japan; in the EU, product information files must also contain data on the safety of ingredients and products). In Japan, no safety or efficacy data is needed once registration of an ingredient has been obtained. In the USA and Japan, specific stability tests must be carried out; in the USA, data on stability and efficacy are only required to be made available on request.

GMP

GMP for pharmaceutical products must be followed for the manufacture of OTC and non-prescription drugs in the USA and Canada, even where the manufacturers' premises are located outside the country, and is recommended for quasi-drugs in Japan. Japanese GMP (for both pharmaceuticals and cosmetics) has been developed by industry. In the USA and Canada (as in the EU), pharmaceuticals GMP has regulatory force. Inspection of compliance with Canadian pharmaceutical GMP for manufacturing plants in the EU is carried out by the regulatory authorities in each Member State, in line with European pharmaceutical GMP, through bilateral agreements (Canadian and EU pharmaceuticals GMP are similar). The US FDA remains responsible for inspection of compliance with USA GMP in plants anywhere in the world manufacturing products for sale in the USA. It has the right to inspect manufacturers' premises outside the USA.

4. IMPLICATIONS OF DIFFERENCES IN REGULATORY FRAMEWORKS

4.1 Impacts for Stakeholders

4.1.1 Introduction

Differences in regulatory frameworks for cosmetics have implications for stakeholders because of the global nature of the cosmetics industry. International trade in cosmetics is significant, and multinational companies account for over 80% of cosmetics production in the EU, for example. This global market means that there can be significant benefits for industry in developing 'world' products, that can be sold across the various markets. Differences in regulatory frameworks can hinder this process, resulting in:

- reduced ranges of products available for consumers;
- enforcement problems for regulators because products imported into their country may not comply with local regulatory frameworks;
- increased costs and marketing delays for manufacturers and importers; and
- constraints on innovation (discussed in detail in Part IV of this Report).

This Section examines these impacts, based on consultation with regulatory authorities and industry associations in each of the main markets, with individual companies (including multinationals) and with an EU consumer organisation.

4.1.2 Impacts for Regulatory Authorities

The main impact of differences in regulatory frameworks for regulatory authorities is the need to ensure that imported products comply with applicable regulations. Given the significant level of international trade in cosmetics, this can pose a considerable workload.

For countries with OTC/quasi-drug categories, it may involve checks on ingredients and claims made to ensure that products meet the limited definition of cosmetics. Differences in permitted ingredients also mean that authorities cannot assume that products sold in other markets meet the requirements in the importing market.

Differences in regulatory frameworks also mean that each regulatory authority may have to carry out its own evaluation and assessment procedures. For example, a new cosmetic ingredient may have to be assessed in terms of its safety, even though it has already been approved for use in another market. Similarly, regulatory authorities may have to develop their own guidance and standards (for example on testing procedures, GMP, etc) and, in some cases, to enforce the implementation of these in other countries. Again, these factors will add to the costs and other resource requirements for regulators.

Finally, certain approaches to regulation of cosmetics are inherently more demanding on regulators. This applies in particular to systems of pre-market approval. One reason for the deregulation of cosmetics in Japan was the increasing workload involved in pre-market approval of the growing number of cosmetic products.

None of the regulatory authorities consulted indicated that differences in regulatory regimes in the major markets resulted in significant differences in consumer safety. However, the authorities in Canada indicated that one reason for developing the Ingredient Hotlist, based largely on the EU prohibited and restricted lists, was to provide better guidance to industry on safety. The EU lists were selected as the basis because they were known to offer a high degree of safety and because a harmonised list was considered beneficial. However, the lists were reviewed in detail before adoption, to ensure that they reflected any specific Canadian concerns.

4.1.3 Impacts for Consumers

The EU consumer organisation indicated that the main concern of consumers in relation to the regulation of cosmetics is to ensure the safety of products placed on the market. There appears to be a good degree of satisfaction with the safety of products on the EU market. Most consumers' experience of markets outside their home country is limited, though, so the organisation was unable to comment on the relative merits of different regulatory approaches or on the impacts of differences on product availability.

Industry has highlighted some of the implications of regulatory differences for consumers. These include:

- differences in product ranges available in different countries, with some consumers not having access to more recently developed (and potentially more effective) products;

- differences in the type and nature of information available to consumers, for example Canadian consumers do not currently need to be provided with full ingredient lists for cosmetics whilst consumers of OTC products in the USA receive 'drug facts' information that industry considers inappropriate; and

- increased product prices because of the costs associated with product reformulation, additional testing, packaging, labelling and advertising changes associated with differences in regulatory regimes.

4.1.4 Impacts on Industry

The most direct impacts of differences in regulatory frameworks for cosmetics are borne by the industry. During the study, industry associations and individual companies in the four main markets were asked to identify the positive and negative aspects of current regulatory frameworks for cosmetics.

There was a clear preference amongst cosmetics companies for a broad definition of cosmetics, as in the EU Cosmetics Directive, with clear separation of cosmetics and drugs and no intermediate categories.

The cosmetics industry argues that the classification of products as OTC, non-prescription or quasi-drugs does not necessarily result in either an increase in consumer protection or in higher standards of safety for the products. In practice, the additional requirements for these product categories (such as pre-market approval and limits on the ingredients that can be used) do not provide greater protection than is provided under the EU Directive. The introduction of an extra product category between cosmetics and drugs also results by definition in more borders (with the corresponding regulatory difficulties) compared with the single border between drugs and cosmetics under the EU regulatory framework.

Manufacturer responsibility for product safety, rather than the shared responsibility that results from systems requiring pre-market approval, is seen by industry as the most effective and flexible approach. Industry favours the USA cosmetics regulation approach, of few ingredient prohibitions or restrictions. Similarly, the USA/Canada approach of no positive lists, with any use of ingredients permitted as long as it is safe, is seen as beneficial. However, industry recognises that this approach appears to be acceptable to regulators only for a limited range of product categories and may not be compatible with a broad definition of cosmetics. If there are to be prohibitions and restrictions, the EU approach of clear, published, lists is seen as providing the greatest certainty for manufacturers.

Industry believes that cosmetics should be regulated on the basis of safety rather than efficacy, as it is difficult to achieve consensus on efficacy and cultural differences mean that efficacy claims in advertising are best regulated at national level. Although the extent to which safety testing requirements for cosmetics are specified differs, in practice broadly similar approaches are adopted everywhere. Additional testing is generally only required when problems arise. By contrast, testing regimes for OTC, non-prescription and quasi-drugs are seen as potentially inappropriate for cosmetic-type products, adding significantly to costs and delaying entry of products onto the market whilst not enhancing product safety.

A harmonised approach to labelling, based on INCI terms with no translation and metric quantity information, is strongly favoured by industry. There were criticisms of the Canadian dual-language labelling requirements (which apply to non-scientific names such as ‘water’) and Japanese requirements for transliteration of INCI terms.

Industry associations and individual companies were also asked about the implications for their businesses of differences in regulatory regimes. These are discussed in detail below.

4.2 Industry Responses to Differences in Regulatory Frameworks

4.2.1 Types of Action Required

Industry consultees were asked to provide examples of the types of actions that they had taken in response to differences in regulatory regimes, and the business implications of these. These included:

- changes to product formulations;
- changes to packaging;
- changes to labelling;
- changes to advertising (claims made);
- additional safety testing; and
- not placing products on the market in certain countries.

Examples of the countries (including both the main markets and other markets) and types of products for which these actions were taken are given in Table 4.1.

Table 4.1: Actions Taken in Response to Differences in Regulatory Regimes

Action	Country	Product	Details
Changes to product formulation	US	Sunscreen products	Reformulation to use permitted UV filters
	Japan	Hair colours, permanent wave products	Reformulation to comply with ingredient restrictions
	Japan	All products	Reformulation to use permitted preservatives
Packaging changes	Japan	Aerosols	Replacement of product with an alternate package to comply with Aerosol Regulations
	USA, Canada	Moisturiser with UV filters	Specific packaging required for these markets only
Labelling changes	Japan	Hair care products	Addition of specific aerosol warning to label
	Canada	Hair care products	Addition of French language version of non-INCI ingredients (e.g. 'water')
	USA	OTC products	Provision of information in 'drug facts' format
Advertising changes	Japan	Quasi-drug products	Removal of claims not allowed in Japan (only specified claims are permitted for specific ingredients)
	UK	Skin care products	Anti-oxidant claims not recognised
	US, Canada, Japan, Australia	Skin care products with UV filters	Changes to warnings, SPF numbers
Additional safety testing	EU, Canada	Various	Testing of ingredients under procedures for notification of new substances
	Korea, Taiwan, South America	Skin care products with efficacy claims	Provision of additional information and/or additional testing to meet competent authority requests
	Japan, USA	Skin care products	Additional animal tests required to demonstrate safety
Not placing product on market	US, Canada, Australia, Japan	Skin care products with UV filters	Products not placed on the market because of advertising/claims limitations

Actions such as these can have significant costs, although it proved difficult to quantify these, for a number of reasons. For example:

- changes in product formulations have variable costs, depending on the number of ingredients that need to be replaced and whether alternative ingredients are a straight forward substitute or require other changes to maintain product characteristics;

- the losses in sales that arise because re-formulated products are less effective are very difficult to calculate; and

- the costs of carrying out additional testing can be quantified (and may run into hundreds of thousands of Euro) but the sales lost through delays in marketing a product are less clear.

In general, the differences in regulatory regimes increase the cost and complexity of product development and make product and logistics management more difficult. The regulatory differences with the most significant impacts relate to product categorisation and variability in permitted ingredients. These are discussed further below.

4.2.2 Actions Associated with Product Categorisation

Some of the most significant impacts are associated with the categorisation of products as OTC, non-prescription or quasi-drugs rather than as cosmetics. Examples of these actions are illustrated in Table 4.2.

Table 4.2: Impacts of OTC and Quasi-drug Categorisation for Industry

Country	Product Type	Impacts
USA, Japan	Hair colours	Changes to formulations, requiring extensive efficacy testing before marketing
USA, Canada, Australia	Sunscreens	Changes to product formulations, packaging, labelling, advertising; additional safety testing required; certain products not placed on the market
USA	Anti-perspirants	Changes to product formulations, packaging, labelling, advertising
Japan	Any quasi-drug	Additional safety testing can be required

Further information on the impacts associated with different categorisation of sunscreens, hair colours and anti-perspirants are given in the case studies in Section 4.3 of this report.

Industry indicated that pre-market registration of a new OTC or quasi-drug product could incur considerable costs and take a considerable period of time, especially if a product was not the subject of an OTC monograph. In addition, the nature of the registration process, with strict specification of ingredients and manufacturing process, can limit the potential for future product development and thus profitability. This aspect is discussed further in Section 8 of this Report.

4.2.3 Actions Associated with Variability in Permitted Ingredients

Impacts also arise where ingredients are permitted for a particular use in one market but not in others. This was seen by industry as an example of poor harmonisation, indicating that substances safe for consumers in one country were not considered safe for consumers in other countries. Again, consultees were asked to provide examples and Table 4.3 illustrates ingredient types for which variations in regulations are particularly significant.

Table 4.3: Examples of Variability in Permitting Ingredients for Cosmetic Uses

Ingredient	Market Where Banned	Market Where Permitted
Colour additives for eye area cosmetics	USA (very few permitted)	Japan, EU
Various hair colours	Japan	EU
Various preservatives	Japan	USA, EU
UV filters	USA (very few permitted)	EU
Bleaching products	USA (only one permitted, that is not used elsewhere)	EU

Again, the case studies in Section 4.3 provide further details of the impacts of variation in permitted UV filters (with Annex II providing a comparative list of UV filters permitted in the main and some emerging markets) and hair colours.

One of the problems for industry in addressing differences in permitted ingredients in different markets is the lack of straight forward methods of comparison ingredients that can be used in similar products in different markets. For example, the EU and Japan have positive lists of colouring agents, preservatives and UV filters permitted for use in cosmetics. The USA and Canada, by comparison, have no such positive lists. The USA does have a list of permitted colouring agents, but this does not operate in the same way as a positive list. Similarly, the prohibited and restricted lists of ingredients for cosmetics in the EU and Japan, and the Canadian Ingredients Hotlist, are broadly comparable. By contrast, the list of prohibited ingredients in the USA regulations is very short, but it is supplemented by voluntary recommendations from the Cosmetic Ingredients Review.

These differences mean that comparison of ingredients permitted for use in products categorised as cosmetics is already difficult. Where a product is categorised as a cosmetic in one market but as an OTC, non-prescription or quasi-drug in another market, it becomes even more complex. Ingredients permitted for use in OTC and non-prescription drugs in the USA and Canada are specified in OTC monographs. In Japan, however, the list of accepted ingredients for quasi-drugs is partly confidential, with only the lists for oxidative hair dyes, perms, medicated bath products and toothpastes published.

In these circumstances, manufacturers need to have a high level of expertise and experience to ensure that the ingredients contained within their products are acceptable in all the markets that they wish to enter. The issue is further complicated by the fact that both positive and negative lists of ingredients change

over time, in response to new scientific evidence and/or the development of new ingredients. The consequences of these complications is discussed further in the case studies.

4.3 Case Studies

4.3.1 Introduction

In order to illustrate the impacts of regulatory differences for industry, and industry's responses, in more detail, a series of case studies have been prepared in consultation with industry. The case studies cover:

- sun products and products with a sun protection factor (SPF);
- UV filter 4-Methylbenzylidene Camphor (4-MBC);
- hair dyes; and
- anti-perspirants.

These case studies were selected for the following reasons:

- **sun products**: this case study illustrates a number of issues, including different product categorisation in different markets, the lack of a uniform approach to assessing SPF and the impacts of regulatory differences on innovation;

- **UV filters**: these are of particular interest because they are subject to positive listings as cosmetics ingredients in the EU and Japan, whereas they are controlled under monographs or new drug application procedures in the USA and Canada. This has resulted in significant differences between UV filters permitted in different markets;

- **antiperspirants**: these products are also categorised differently in different markets; and

- **hair colours**: as well as differences in categorisation, these products face differences in the ingredients permitted in different markets, with implications for re-formulation as well as changes to packaging, advertising and claims.

The case studies provide background on the product, outline the main regulatory issues and their implications for business, discuss the impacts on market access and competitiveness and, where relevant, identify actions that could be taken to address the impacts and initiatives that are currently under way.

Where relevant, the case studies also make reference to regulatory differences in third countries, with further information on regulatory requirements in third countries provided in Part III of this Report.

Case Study 1: Sun Products and Products with an SPF

Background

The case study covers sun protection products containing UV filters and moisturisers, lotions and creams with a sun protection factor (SPF), including sun tan creams, oils and lotions. They are intended to protect against skin damage by UV rays and are widely used in the major markets (EU, US, Japan and Canada) by all age groups. Moisturisers, lotions and creams with a SPF have the dual function of hydrating the skin as well as protecting against skin damage by UV rays.

No data are currently available on the size of the EU market for sun products and products with a SPF; in the EU, skin care products as a whole account for 23% of the total cosmetics and toiletries market and are the fastest growing segment (Colipa, 2003). Sun protection products are experiencing rapid technical development associated with the introduction of new, more effective UV filters.

Regulatory Issues

These products are regulated as cosmetics (subject to positive lists) in the EU and Japan, as functional cosmetics in Korea, as OTC drugs in the USA and Canada and as OTC products in Australia if the SPF is greater than 4. The SPF gives an indication of how much sun protection the product offers; this is assessed in different ways by the regulatory authorities in the major markets. In the opinion of Colipa, the main methods for assessing SPF give similar results, even if certain technical details are not identical.

UV filters are subject to positive lists or prior approval in all markets and only listed UV filters can be used (see Case Study 2). There are considerable differences in the data requirements and timescales for approval of new UV filters between markets. These are summarised in Table 4.4.

In the USA, only two new filters have been accepted for use since the proposed Sunscreen OTC Products Monograph was first published in the 1978. Other editions of this monograph have been published but a final version is not yet available. In this monograph, UV filters are classified as active ingredients. New active ingredients can only be added after several years of use in a drug authorised under a New Drug Application. Since 2002 the Time and Extent Application (TEA) has allowed the FDA to accept commercial data obtained in an external market in place of use in an authorised drug in the USA. However, the file data requirements for a TEA are very similar to those for a new drug application, so that there is little change to the time and data requirements (see also Case Study 2).

Actions taken by business to address these differences in regulatory requirements include:

- changes to product formulations, including different UV filter combinations;
- changes to labelling: different labelling of ingredients (and preservatives) and different labelling claims. For example, anti-ageing claims for daily face care products with UV filters, which are allowed in the EU, cannot be made in the USA. Similar changes must be made to advertising claims; and
- additional safety testing: performing SPF measures in line with specific local methodologies.

Market Issues

The key implication is that products in this market must be tailor-made for the specific market and that companies cannot rely on a 'global product formula'.

In the case of the US market, some companies carry out additional development work and, in fact, develop separate products using different UV filter combinations.

Potential Actions to Address the Issues

Work on harmonisation of SPF methods is underway. Colipa, CTFA-SA and JCIA have agreed a common approach (Colipa, 2003).

Table 4.4: Timescales and Requirements for Approval of New UV Filters		
Market	**Time Required**	**Data to be Submitted**
EU	Preparation of the file: **2 - 3 years** Approval by the SCCNFP after submission of the complete file: **approximately 1 year**	Acute toxicity Percutaneous absorption Mucous / cutaneous irritation Cutaneous sensitization Subchronic toxicity Mutagenicity (2 tests) Phototoxicity/photosensitization/photomutagenicity Data on effects on men (if available) If some of the previous tests give bad results, the file has to be completed with the following tests: - Toxicokinetics - Teratogenicity/Reproduction/Carcinogenicity /Genotoxicity
USA	Preparation of the file: **5 - 7 years** Approval by the FDA after submission of the complete file: **approximately 1 year**	In addition to the elements required for the EU, it is necessary to provide FDA with any additional safety and tolerance tests requested.
Canada	Files accepted in the USA are accepted in Canada, and vice versa.	Same data as in the EU/USA
Japan	Approval by the Ministry of Health after submission of the complete file: **approximately 2 years**	In addition to the data required in the EU: - Test of tolerance on Japanese skin - Repeated skin irritation test (14 days on guinea pig)
Korea	Approval by the Ministry of Health after submission of the complete file: **approximately 1 year**	Specifications of the raw material in English Analytical file (analytical method, impurities) Efficacy data of the ingredient in the finished product 6 months stability tests using the Korean method
Australia	Approval by the Therapeutic Goods Administration (TGA) after submission of the complete file: **approximately 4 months + NICNAS: some days**	Same data as in the EU/USA for TGA plus ecotoxicity data for inclusion on the Australian Inventory of Chemical Substances

Case Study 2: UV Filter 4-Methylbenzylidene Camphor (4-MBC)

Background

The case study covers an organic UV filter, Tradename Eusolex® 6300 (CAS No. 36861-47-9). 4-MBC is used in sunscreen products (lotions, creams, sprays, oil, lip balm) to protect the skin against damage by UV rays. 4-MBC can also be used in cosmetic products for product protection purpose.

Currently there are 26 approved organic UV filters in the EU, in the USA and 28 in Japan. Ten UV filters are approved in all three countries. Taking Canada, Korea and Australia into account, only nine UV filters are internationally approved . The UV filters approved in all markets are those which have a long history of use. None of the new UV filters are internationally approved. In addition to these organic UV filters, two inorganic UV filters are approved or at least permitted for the use in all countries. Annex 2 presents a comparative list of UV filters approved in different markets.

Regulatory Issues

UV filters are subject to positive listings or prior approval in all markets. Products containing UV filters are regulated as cosmetic ingredients in the EU and Japan, as functional cosmetics in Korea, as OTC drugs in the USA and as non-prescription drugs in Canada (see Case Study 1 and Table 1.1). 4-Methylbenzylidene Camphor is approved in the EU, Canada and Korea.

In the **EU** 4-MBC has been on the market for more than 30 years. It was included on the positive list for UV filters when this was first established in 1982. 4-MBC was evaluated by the SCCNFP in 1998 and finally approved for use at a concentration of 4%. It is now being re-evaluated by the SCCNFP.

In the **USA,** 4-MBC has a long regulatory history. It was on the market for a short period in the mid 1970s before the tentative monograph for 'Sunscreen Drug Products for Over-The-Counter Human Drugs' was published in 1978. Initial submissions were made in response to the call for data at the outset of the OTC sunscreen monograph process. Based on these submissions, the panel found that 4-MBC is safe and effective and recommended that it have Category I status. This Category I status was changed in 1978 on the basis that there was no data establishing the marketing of Eusolex® 6300 in the US prior to 4 December 1975.

In response to that change in the status of Eusolex® 6300, a Citizen Petition was filed requesting reconsideration and seeking to reopen the rulemaking process. During the following years, extensive additional submissions were made in support of the safety and efficacy of 4-MBC. The 1999 submission included the studies that formed the basis for the final approval of 4-MBC in Europe by the SCCNFP in 1998.

On 23 January 2002, the FDA published a Final Rule ("Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as generally Recognized as Safe and Effective and Not Misbranded") with which companies were invited to submit market data for OTC drug substances under a TEA (Time and Extent Application). The TEA for 4-MBC was submitted in August 2002 and its acceptance was followed by a call-for-data from the FDA (safety and efficacy). The safety data were submitted in October 2003, together with a request for an interim marketing because 4-MBC was originally classified as safe (Category I) when the monograph was established. The request for interim marketing was refused by the FDA and the approval process is now pending until the safety data have been evaluated.

The alternative approach to obtain the approval of 4-MBC was and still is a New Drug Application. This approach, however is a high-cost and time-consuming approach, resulting in the approval of only one consumer product. This is not economically viable for sunscreens and has been used only for one UV filter within the last 30 years.

4-MBC is not approved in **Japan**. Until deregulation in April 2001, the only way to obtain approval of an UV filter was as an active ingredient within a consumer product. Unfortunately, the Japanese approval process was neither transparent nor easy to understand at that time. European companies found it very difficult to obtain approval for an UV filter without the support of a Japanese cosmetic company. In 2001, cosmetics legislation was deregulated and is now close to the European regulation. Since that time no new approach for the approval of 4-MBC has been made.

Market Issues

4-MBC is of limited interest to international cosmetic companies because of the limited approval to date and the non-predictable time frame for obtaining approval in the USA and Japan. Consumers outside Europe do not have easy access to 4-MBC-containing products. Similar constraints apply to a number of newly-developed UV filters.

4-MBC and certain new filters are less competitive on the international market compared to established UV filters, because of their limited approval. Interest in investing in R&D on new UV filters is low, because access to the USA market in particular requires a timescale that often exceeds the length of patent protection. The USA market does not grant any data protection for newly-approved UV filters on the market. Consequently there is no incentive for companies to invest in the registration process.

Potential Actions to Address the Issues

Actions to address these issues could include:

- mutual recognition of the approval of UV filters, at least between the major countries;
- comparable registration requirements in all countries, using internationally-accepted guidelines and with comparable and reliable registration procedures and time at the authority level; and
- data protection for those companies that have invested in registration.

Case Study 3: Hair Dyes

Background

This case study concerns cream, lotion or spray direct or oxidation hair dyes for changing the colour of the hair, either permanently or temporarily.

No specific data are available on the market for hair dyes. Hair care products as a whole account for nearly 25% of the EU cosmetics and toiletries market and hair colouring products are a very important segment within this category. The hair care category is the cosmetics segment with the second highest growth rate within Europe.

Regulatory Issues

Hair dyes are categorised as cosmetics in the EU and USA. In Japan, Korea and China their classification depends upon whether they are oxidation dyes or direct dyes. In Japan and Korea, oxidation hair dyes are classified as quasi-drugs/functional cosmetics respectively whilst direct hair dyes are classified as cosmetics. In China, oxidation hair dyes are classified as special purpose cosmetics and direct hair dyes as ordinary cosmetics. The impacts of these differences in terms of regulatory requirements are summarised in Table 4.5.

Actions required of manufacturers in response to the differences in regulations include:

- pre-market approval of certain products in Japan and Korea and of all products in China;
- changes in active ingredients to comply with different restrictions (particularly in Japan, where the short positive list of permitted active ingredients include several banned in the EU, such as *2-Amino-4-Nitrophenol*);
- different labelling of ingredients (designated ingredients only are to be labelled for oxidation dyes in Japan and for all products in Korea and China, whilst all ingredients must be labelled using INCI terms in the EU and USA and in Japanese in Japan); and
- differences in the warnings to be provided with the product. For quasi-drugs in Japan and Korea, the prescribed warnings are very lengthy.

Market Issues

The key implication is that products in this market must be tailor-made for the specific market and that companies cannot rely on a global product formula. New products in line with consumer trends cannot be launched in Japan, Korea or China at the same time as in the rest of the world. Separate product development is required for these countries in order to compete with local manufacturers. Development of specific formulas for Japan requires additional R&D capacity (costs depend on the number of products sold in Japan). Preparation of physico-chemical, safety and stability data is required for Japan only in the case of registration of a new hair dye (about €0.5 to 1 million per substance).

Potential Actions to Address the Issues

Actions that could be taken by the European Commission to address the issues include:

- encouraging Japan to deregulate quasi-drug hair dyes as it deregulated cosmetics in 2001;
- encouraging China to transfer responsibility for general cosmetics and special purpose cosmetics to the manufacturer and to strengthen post-market surveillance in order to replace pre-market registration procedures (including quality and safety tests; see also Section 6.1); and
- encouraging Korea to re-classify oxidation hair dyes as cosmetics (see also Section 6.4).

Ongoing actions to address the issues include international conferences, meetings with health authorities and industry associations, for example the international conference of Mutual Understanding in Tokyo in October 2003 and the meeting between Chinese MoH and EU companies on hair dye issues in November 2003.

Table 4.5: Regulatory Status of Hair Dyes in Major and Emerging Markets								
	EU	**USA**	**Japan**		**Korea**		**China**	
Classification	Cosmetic	Cosmetic	Quasi-drug (oxidation hair dyes)	Cosmetic (direct hair dyes)	Functional Cosmetic (Oxidation hair dyes)	Cosmetic (direct hair dyes)	Special purpose cosmetics (oxidation hair dyes)	Ordinary Cosmetics (direct hair dyes)
Ingredient Restrictions	17 active ingredients prohibited under Annex II; 66 ingredients or families of ingredients subject to restrictions under Annex III. Evaluation of all active substances by SCCNFP completed	No restrictions for "coal tar hair dyes" which correspond to synthetic organic compounds. Hair dyes from mineral or vegetable origin must be listed on the positive list of cosmetic colorant agents	Positive list of 55 active ingredients (includes several substances banned in the EU). New active ingredients and additives have to be approved through a lengthy procedure and to comply with raw material standards	No restrictions; voluntary registration of direct hair dyes with JCIA	Positive list of active ingredients. New active ingredients have to be approved and additives must comply with raw material standards	No restrictions, as long as ingredient appears in Korean Standards of Cosmetic Ingredients or International Cosmetic Ingredients Directory	Restrictions for several active substances (similar to EU Cosmetics Directive up to the 25th Adaptation)	Restrictions for several active substances (similar to EU Cosmetics Directive up to the 25th Adaptation)
Procedure	Notification before marketing. Product Information Dossier to be maintained	Voluntary cosmetic registration programme	Pre-market approval for each product	Notification before marketing	Pre-market approval for each product. Imported products require an import licence for each consignment	No pre-market approval; composition and specification must be kept available for inspection. Imported products require an import licence for each consignment	Quality and safety testing (including animal testing) followed by pre-market approval for each product	Local products: notification of finished product Imported products: quality and safety testing (including animal testing) followed by pre-market approval for each product

Table 4.5: Regulatory Status of Hair Dyes in Major and Emerging Markets								
	EU	**USA**	**Japan**		**Korea**		**China**	
Warnings	Warnings for certain ingredients specified in Annex III; voluntary warning proposed by industry association	Specific warning required	Specific (lengthy) warning required	Voluntary, by manufacturer	Specific (lengthy) warning required	Specific warning required	Not specified	Specific warning required
GMP	Cosmetic GMP	N/a	N/a	N/a	N/a	N/a	N/a	N/a
Distribution	No restrictions	No restrictions	No restrictions	No restrictions	No restrictions	No restrictions	No restrictions	No restrictions

Case Study 4: Anti-perspirants

Background

Anti-perspirants are applied primarily to the underarms as a roll-on, spray or stick. They contain ingredients to limit perspiration and prevent body odour. No data are currently available on the size of the EU market for anti-perspirants, but in the EU, toiletries as a whole (including anti-perspirants) account for around 25% of total cosmetics sales. Toiletries are not amongst the most rapidly growing sectors of cosmetics and have not experienced a high rate of innovation.

Regulatory Issues

Anti-perspirants are classified as cosmetics in the EU, OTC drugs in the USA, quasi-drugs in Japan, functional cosmetics in Korea and exempt therapeutic goods in Australia. The differences in classification have implications for regulation of ingredients, pre-market approval of products, data required to be submitted to the authorities and Good Manufacturing Practices to be followed. These differences are summarised in Table 4.6.

Actions required of manufacturers in response to the differences in regulations include:

- pre-market approval of anti-perspirants in Japan and Korea (however, the USA monograph system makes it possible to market without pre-market approval subject to restrictions);
- licensing of manufacturers/importers in Japan and Australia and registration of the establishment and product list in the USA;
- changes in active ingredients to comply with different restrictions; and
- compliance with different requirements relating to GMP.

Market Issues

By careful consideration of the requirements of each country, it is possible to produce formulations that are legally acceptable in all markets (though product and ingredient formulations may not be readily transferable to Japan due to specific consumer preferences). The main differences in market access are the different labelling needs and registration requirements. Sometimes, however, claims used in the USA must be modified for the EU market to prevent products falling under the Medicinal Products Directive. Claims substantiation data requirements may also be different in the USA and EU.

A requirement for pre-market registration tends to favour the home producer, for logistical reasons, even where this is not intended. Different performance test requirements in different markets lead to unnecessary extra costs. Labelling requirements coupled with (usually) small pack size make a global pack almost impossible, increasing costs and reducing economies of scale.

New developments which deviate significantly from standard practice, e.g. new active ingredients, are difficult to achieve, depriving heavily regulated markets of innovation. For maximum flexibility, separate formulations are required for different markets.

Potential Actions to Address the Issues

Given their generally safe nature, anti-perspirants should be regulated as cosmetics, or at least as drugs exempt from registration and labelling requirements. Individual materials should be controlled or prohibited in the light of known problems; otherwise, any active ingredient should be permitted subject to efficacy studies. Working towards harmonisation of permitted ingredients would reduce the impacts of regulatory differences.

Since most of the authorised test methods are similar, either a single standard method should be agreed or there should be mutual recognition of data obtained from different methods. Harmonising the principles of testing, through at least common minimum requirements (data requirements, basic principles of risk assessment, acceptable margins of safety) could simplify approval in one country of substances already approved in another.

Table 4.6: Regulatory Status of Anti-perspirants in Major and Emerging Markets					
	EU	**USA**	**Japan**	**Korea**	**Australia**
Classification	Cosmetic	OTC drug	Quasi-drug	Functional Cosmetic	Exempt therapeutic good
Ingredients	Aluminium/ zirconium salts subject to restrictions on use.	Active ingredients must be registered.	Active ingredient must be approved; list of additives in place.	Notified ingredient list exists. Ingredients listed in Korean or Japanese official inventory may be used as additives.	Can only be an anti-perspirant if it contains aluminium, zirconium or zinc salts. Ingredients must be listed on Register of Therapeutic Goods (RTG).
Procedure	Notification before marketing. Product Information Dossier to be maintained including formula, specification, manufacturing method, safety, stability and efficacy data.	Pre-market approval required. Data to be submitted in line with New Drug Approval requirements. Registration of the manufacturing establishment and product list are mandatory.	Approval required before marketing. Data required on active ingredient, its origin, physico-chemical properties, stability, safety and effects. Also product formula, specification, manufacturing method and safety data. Manufacturer/importer must have licence.	Approval required before marketing. Data required on active ingredient, its origin, physico-chemical properties, stability, safety and effects. Also product formula, specification, manufacturing method and safety data, together with product efficacy.	Ingredients not on RTG must be presented for assessment and approval. Manufacturer/importer must have a licence.
GMP	Cosmetic GMP	OTC Drug GMP	Cosmetic GMP	N/a	Drug GMP
Distribution	No restrictions	No restrictions	No restrictions	No restrictions	No restrictions

PART III

PROPENSITY OF THIRD COUNTRIES TO MODEL THEIR RESPECTIVE LEGISLATION AFTER PERCEIVED LEAD LEGISLATION

5. SIGNIFICANCE OF THIRD PARTY MARKETS FOR COSMETICS

5.1 EU Trade in Cosmetics with Third Countries

Although the major markets (the EU, USA, Japan and Canada) account for a large proportion of total world cosmetics sales, third countries represent significant and growing markets. Table 5.1 sets out exports of cosmetics from the EU to major markets and third countries in 2001.

Table 5.1: Exports of Cosmetics from the EU in 2001

Region	Value (€ million)	Percentages
USA	1,425	20%
Middle East[1]	910	13%
Asia (excluding China and Japan)	940	13%
Eastern Europe[2]	875	12%
Japan	440	6%
Africa	335	5%
South and Latin America (excluding Mercosur Countries)	325	5%
Australasia	230	3%
Mercosur[3]	225	3%
Canada	195	3%
China	25	>1%
Other Countries	1,237	17%
Total[5]	**7,160**	**100%**

[1] Middle East countries include: Lebanon, Syria, Iraq, Iran, Israel, Gaza & Jericho, Jordan, Saudi Arabia, Kuwait, Bahrain, Qatar, United Arab Emirates, Oman and Yemen.

[2] Eastern European countries include: Romania, Bulgaria, Albania, Ukraine, Belarus, Moldova, Russia, Georgia, Armenia, Azerbaijan, Kazakhstan, Turkmenistan, Uzbekistan, Tajikistan and Kyrghistan.

[3] Mercosur countries include: Brazil, Argentina, Paraguay, Uruguay and Chile.

[4] Exports to the New EU Countries have not been included; these account for approximately €895 million.

Source: Eurostat (2003)

The key market regions for European cosmetics outside Europe (where regulatory frameworks for cosmetics are broadly similar to those in the EU) and the other major markets include the Middle East, Asia and Eastern Europe. However, it is not only the current size of markets that is significant for cosmetics trade, equally important is the potential for future growth.

5.2 Size and Potential Growth of Markets

5.2.1 Eastern Europe

Exports from the EU to Eastern Europe comprised approximately 12% of total extra-EU exports in 2001. Table 5.2 outlines available information on the main cosmetics markets in Eastern Europe. Accurate statistical data on markets in Eastern Europe remain sparse. The information in the Table was obtained from a range of sources, which are not necessarily compatible, and thus should be regarded as indicative only.

Table 5.2: Cosmetics and Toiletries Markets in Eastern Europe

Market	Population (million)	Value (€ million)		
		Market Size	Total Imports*	Imports from EU
Russia	143	1,345 – 4,480	455	580
Ukraine	48	784	64	98
Kazakhstan	17	-	30	21
Belarus	10	-	21	12
Other countries[1]			70	164
Total	**223**		**640**	**875**

[1] Other countries include: Romania, Bulgaria, Albania, Moldova, Georgia, Armenia, Azerbaijan, Turkemenistan, Uzbekistan, Tajikistan and Kyrghistan.
Sources: Eurostat (2003), *ITC International Trade Statistics. Note: Discrepancies in data may be due to differences in definitions and scope between different data sources.

The most significant Eastern European markets in terms of population and total cosmetics market size are Russia and Ukraine. Croatia appears to have higher levels of imports than Ukraine, but this reflects a very high level of import penetration and limited future potential for growth. By contrast, Russia and Ukraine both have considerable potential to increase their share of imports from the EU.

The beauty and health product market has been one of the fastest growing in Russia, with annual growth rates in the years to 2001 averaging 20% per year, compared to 2% per year in Western Europe. Value sales were forecast to grow by a further 10% in 2002. Volumes of professional cosmetic products purchased by beauty salons are also reported to be growing at very high rates. The total volume of the market has been estimated at anything up to $4 billion, with up to 50% of the market accounted for by foreign brands, which include local production by international companies as well as imports. Previously, foreign brands accounted for an even higher share of the market, as Russian consumers traditionally trusted foreign brands more to guarantee stable quality. More recently the improved quality of local brands, together with lower prices, has improved their competitiveness. Counterfeiting remains an issue, with some estimates indicating that up to 40% of beauty products on the market are counterfeit.

After the economic crisis of 1998, the Ukrainian market for cosmetics and perfumes shrank from approximately $700 million in 1997 to $490 million in 1999. Since 2000, however, the market has grown and by 2001, it was estimated to be back to its previous size (there are no accurate statistical data on the market). Around 70% of sales is

accounted for by mass-market products at low prices. Imported products account for the remainder, and are especially strong in make-up, deodorants, hair dyes, toothpaste and selective perfumes.

5.2.2 Asia

Table 5.3 sets out information on the cosmetics markets in Asia, including market size and import penetration. Again the information should be treated as indicative only, as it is drawn from different sources that are not necessarily based on a consistent approach.

Table 5.3: Cosmetics and Toiletries Markets in Asia

Market	Population (million)	Value (€ million)				
		GDP/head	Market Size	Total Imports*	Imports from US	Imports from EU
Japan	127	37,299	11,981	1,075	302	438
China	1,275	919	5,500	75	49	24
Korea	47	8,918	3,623	475	157	271
India	1,014	515	950	55	12	12
Thailand	63	1,825	620	108	22	36
Hong Kong	7	24,080	500	691	92	191
Malaysia	22	3,891	352	203	44	35
Singapore	4	20,738	351	557	95	194
Philippines	76	926	225	83	19	13
Taiwan	22	12,599	216	n/a	44	135
Total	**2,657**	**-**	**24,318**	**3,322+**	**836**	**1,349**

Sources: USCS (2003); *ITC International Trade Statistics

China represents the next largest Asian market after Japan. The market has grown significantly in the past 20 years, increasing from only $25 million in 1982 to the current multi-billion level. Recent annual growth has been in the region of 15%-20%. Imports account for approximately 30% of the market, with a further 30% accounted for by joint ventures between major international companies and Chinese enterprises. Local brands account for the remaining 40%.

Korea is also a significant market for imports of cosmetics, though there are concerns about the impacts of regulations in restricting imports (discussed further in Section 8.3 below). Korea is a more mature market than China, with potentially less scope for growth.

Other Asian markets are significantly smaller than the top three. Levels of imports into Hong Kong and Singapore are high, but the total market is relatively small and thus prospects for future growth are probably more limited. India has a large population but low GDP per head has limited the growth of the cosmetics market, which was only opened up to imports in 1999.

5.2.3 Other Markets

Table 5.4 summarises information on markets for cosmetics in the Middle East and Latin America, the other main markets for the EU cosmetics industry.

Table 5.4: Imports of Cosmetics into Markets in the Middle East and Latin America (2001)

Country	Value (€ million)	
	Total Imports	Imports from EU
Middle East		
Saudi Arabia	349	235
Kuwait	142	55
Lebanon	78	54
Oman	66	18
Bahrain	48	24
Total	**684**	**386**
Latin America		
Mexico	661	89
Venezuela	186	43
Brazil	168	86
Chile	142	38
Argentina	139	47
Colombia	118	17
Total	**1414**	**320**

The EU appears to account for a large proportion of cosmetics imports into the Middle East. This probably means that there is limited potential for further growth in exports to these countries.

However, the EU's share of exports to Latin America is much lower. The USA is likely to be the major source of competition in these markets, particularly in Mexico, the largest market in the region, due to its membership of NAFTA. Nevertheless, Latin American markets and in particular Mexico and Brazil remain of considerable interest to EU cosmetics exporters.

5.3 Selection of Markets for Detailed Review

The terms of reference for this study called for two third country markets to be studied in detail. The initial view was that, on the basis of market size and form of legislation, these should comprise either Russia or Ukraine together with either China or Korea. However, Latin America was also identified as an area of interest. During discussion with stakeholders, the following comments were made:

- **Russia**: cosmetics regulations are about to be significantly revised. An in-depth study based on the current regulations would therefore be of limited value;

- **Ukraine**: was not seen as a sufficiently significant market to merit detailed study, although general information would be welcome;

- **China**: although small at present, this market has significant potential and its regulatory regime is rather different from that of other markets;

- **Korea**: a revision of the Cosmetics Act is planned that is likely to significantly expand the scope of the cosmeceuticals category. A focus on Korea at this stage would therefore be premature; and

- **Mercosur countries**: these countries are of interest in terms of harmonisation of regulations between countries and the overall direction that this is taking.

Stakeholders therefore agreed that detailed analysis of emerging markets would focus on China and the Mercosur countries (particularly Brazil and Argentina) but that general information would be gathered on issues associated with regulatory frameworks in a wider range of emerging markets. During subsequent discussions with stakeholders, it became clear that plans for harmonisation of regulatory frameworks for cosmetics in ASEAN were also of considerable interest. The next section of this Report therefore sets out detailed information on regulatory frameworks for cosmetics in China, Mercosur and ASEAN.

6. REGULATORY FRAMEWORKS IN THE EMERGING MARKETS

6.1 The Regulatory Framework in China

6.1.1 Definition of Cosmetics and Borderlines with Other Regulations

Introduction

Cosmetics legislation in China is currently under review, and may be subject to considerable change in the near future. Because plans for future changes have not yet been finalised or published, this Section describes the current regulatory framework.

Legislation in China identifies two main categories of products:

- cosmetics (including the specific sub-category special use cosmetics); and
- drugs.

Cosmetic Products

Current regulations define cosmetics as:

> '*those daily used chemical products applied on the surface of any part of the human body (such as skin, hair, nails and lips) by way of smearing, spraying or other similar methods to keep the body clean, to get rid of undesirable smell, to protect the skin, to make up the face and to increase the beauty of the appearance*'.

Cosmetics are divided into two sub-categories: ordinary cosmetics and special use cosmetics. Ordinary cosmetics comprise products such as lipstick, nail products, perfume and shampoo. Special use cosmetics include sunscreens, weight loss products, skin creams and hair removal products. Some product types can be either ordinary or special use cosmetics, depending on their composition. For example, direct hair dyes are ordinary cosmetics whilst oxidation hair dyes are special purpose cosmetics (see Case Study 3 in Section 4.3).

Drugs

The regulations define drugs as:

> '*materials which objectively regulate the physiological function of human beings in order to prevent, remedy or diagnose human disease and stipulate the indication, use direction and dosage, including traditional Chinese medicinal materials, herbal pieces for decoction, compound preparations for traditional Chinese drugs, chemical raw drug materials and its preparation, antibiotics, biological products,*

radiopharmaceuticals, blood products, serum vaccine and drugs for diagnosis, etc.'

6.1.2 Regulation of Cosmetics

Introduction

Cosmetics in China are subject to the Regulations for the Hygiene Supervision of Cosmetics (1990), Particulars of Implementation of Hygienic Inspection Regulations for Cosmetics (1991), Particulars of Implementation of Production Licence of Cosmetics (1994) and Hygiene Standard for Cosmetics (1999).

The competent authority responsible for cosmetics is the State Food and Drug Administration (SFDA). The SFDA was formerly known as the State Drug Administration until the name change on 16 April 2003, when additional supervision and administrative functions in food, health products and cosmetics were transferred to it from the Ministry of Health (MoH). SFDA is responsible for protecting public health by assuring the safety, efficacy and security of drugs, biological products, medical devices, food and cosmetics through its regulatory and legal enforcement functions.

Other relevant authorities include the General Administration of Quality Supervision, Inspection and Quarantine (GAQSIQ). GAQSIQ was founded in April 2001 (replacing the State Entry and Exit Inspection and Quarantine Bureau (SEEIQB) and the State Quality and Technology Supervision Bureau (SQTSB)). GAQSIQ is a legal executive authority responsible for import and export duties and quality supervision, commodities inspection, hygiene and quarantine, animals and plants quarantine, certification and accreditation, etc.

Pre-market Requirements

Cosmetic manufacturers in China must be registered and all manufacturing sites must have a Hygiene Licence as well as a Production Licence. The Hygiene Licence is issued by the Bureau of Public Health (BOPH) and takes between six and twelve months to obtain. It is valid for four years and must be submitted for review one year before its expiry.

Product registration requirements differ between ordinary and special use cosmetics and between domestic and imported cosmetics:

- *domestic ordinary cosmetics* do not require pre-market registration. Instead, local authorities must be notified within two months after the product is first marketed;

- *domestic special cosmetics* are subject to a pre-market registration process. A safety assessment is required that should include acute toxicity, animal skin and mucous tests, mutagenic and short-term biological screening tests for carcinogenesis and chronic toxicity, etc. There are specific requirements for each product type. The

safety assessment is undertaken by an Expert Group and other relevant bodies with the actual approval granted by the MoH;

- *imported ordinary cosmetics* require a Hygiene Permit of Imported Cosmetics. When a cosmetic is imported for the first time, foreign manufacturers and their agents are required to submit a Cosmetic Import Health License to the Ministry of Health (MoH)[10]. The cosmetic must undergo an extensive conformity assessment and registration process. Upon approval of the cosmetic, the manufacturer is awarded a production licence (for each product category manufactured at the site and valid for a period of five years) and an approval number. This process could take up to a year. In addition, all imported cosmetics must be registered with the GAQSIQ. This is also a complex process, and can take four to five months; and

- *imported special cosmetics* must follow the same procedures as imported ordinary cosmetics, as well as the pre-market registration process applied to domestic special cosmetics.

Controls over Ingredients

The Hygiene Standard for Cosmetics (1999) lists restricted ingredients including colourants (both permanently and provisionally listed colour additives), UV filters and hair dyes not allowed in cosmetic products. China is indicated to base its lists on the restricted and prohibited lists of the EU Cosmetics Directive. It is currently developing positive lists for various cosmetics ingredients. Full ingredient listing is not required for cosmetics.

Labelling and Warnings

Labels must provide the name and address of the manufacturer or person placing the product on the market; the batch number; nominal net content; country of origin; date of manufacture; usage instructions and warnings and the expiry date. All required information must be in Chinese.

The Chinese HSC regulations (1990) also state that 'No indications, curative effect and medical terms are allowed to be written on the label, on the inner packing or on the specification sheet of cosmetic products'.

Testing and Safety

Article 9 of the Chinese HSC regulations (1990) requires an application to be made to the health administrative department under the State Council for approval before a new kind of material is used to make cosmetics. The term 'new kind of material' refers to natural or synthetic ingredients that are used in cosmetics for the first time in China. All new

[10] As noted earlier, the supervision and administrative functions in cosmetics were recently transferred from the MoH to the SFDA.

ingredients, as well as new approved uses of ingredients, are thus required to undergo a safety evaluation based on specified procedures and methods. The MoH does not accept foreign data and all cosmetic products must undergo testing within China.

Article 31 of the same regulations makes producers responsible for the safety of their products. It states that:

> *'if a consumer is harmed physically or poisoned as a result of violation of the regulations, the production enterprise, the business enterprise or the persons who are directly responsible for the consequences must compensate for the loss. If the case has produced serious consequences, the party responsible shall be prosecuted for criminal responsibility by the judicial organs in accordance with the law'.*

The EU industry has no experience of any successful prosecutions being brought under this provision.

There are no specific GMP requirements for cosmetics manufacture, but a manufacturer must certify GMP compliance when importing a cosmetic.

6.1.3 Regulation of Other Product Categories

The Chinese regulations broadly recognise that some products may be both cosmetics and drugs. The regulations set out specific registration requirements for cosmetic-drugs, which go beyond those for cosmetics. These requirements include the provision of information on:

- product stability;
- preservative efficacy;
- material safety data sheets (MSDS); and
- specifications for raw materials.

Full ingredient labelling is also required for drugs.

6.1.4 Similarities and Differences from Lead Legislation

Alignment with Lead Legislation

Regulation of cosmetics in China is complex, involving two separate government bodies and differences in requirements between imported and domestically-produced cosmetics. The overall approach is not aligned with that of the EU or any other main regulatory models.

Industry is concerned that these differences may increase in future. An inventory and registration system for cosmetics ingredients is currently being established. There is concern that only a small proportion of internationally-used cosmetic ingredients will be included in the inventory. Any additional ingredients will have to be registered with the MoH, which may be a costly and time-consuming process.

Cosmetics legislation distinguishes between ordinary cosmetics, such as lipstick, nail products, perfume and shampoo and special use cosmetics such as sunscreen, hair dye, deodorant, skin creams and hair removal products. This is similar to the Japanese classification of quasi-drugs.

6.1.5 Special Requirements for Imported Products

Under current regulations, imported cosmetics products require registration and approval by the Ministry of Health (MoH). The registration procedure requires the submission of information on formulae, manufacturing details and ingredient specification. Testing is then carried out in MoH laboratories, with the results reviewed by a panel before approval can be given. It can take up to 12 months to complete the process and involves considerable costs. Imported cosmetics must also be registered with GAQSIQ and must display stickers as proof of registration. In practice, when products enter local markets they must be re-approved by the provincial and city branches of the GAQSIQ, which may involve the payment of an administrative fee to the provisional or regional governments. This is not strictly a requirement of the legislation.

Domestic ordinary cosmetics do not undergo this extensive process, they only need to be notified to the local authorities at the place of manufacturing within two months from the launch of the cosmetic product. The registration for imported cosmetics could thus be considered to unfairly discriminate against imported products and is a major obstacle for the introduction of cosmetics into the Chinese market.

Despite the potential difficulties, the EU and other major markets have achieved considerable success in marketing to China (in contrast to some other product sectors).

6.2. The Regulatory Framework in the Mercosur Countries

6.2.1 Regulation of Cosmetics

Mercosur was created by Argentina, Brazil, Paraguay and Uruguay in 1991, with association agreements signed with Chile and Bolivia in 1996. Each of these countries has its own regulations governing cosmetic products, although there exists an agreed framework among the four full members of Mercosur for regulating cosmetics. Table 6.1 summarises the main features of the regulatory requirements for cosmetics in the four initial Mercosur countries.

Cosmetics regulations in the Mercosur share a number of key features:

- harmonised definition of cosmetics;
- harmonised negative and positive lists;
- harmonised labelling requirements (with certain exceptions);
- manufacturers' responsibility for safety of cosmetic products, but with registration of products prior to marketing;

- pre-market registration and/or licensing of cosmetic manufacturing establishments is generally required, except in Argentina where compliance with the relevant regulations results in automatic approval and registration; and
- adoption of good manufacturing practice (GMP).

6.2.2 Similarities and Differences from Lead Legislation

Regulations governing cosmetic products in the Mercosur countries incorporate a number of key features of the EU Cosmetics Directive, including:

- **definition of cosmetic products**: Mercosur adopted a harmonised definition of cosmetics in Resolution No. 31, 1995. It is essentially the same as the EU definition of cosmetics with minor differences between the various countries: '*any substance or preparation intended to be placed 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 exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition'*;

- **controls over ingredients**: lists of prohibited and restricted ingredients, approved preservatives, UV filters and colouring agents are modelled on the EU lists. When updating or amending the lists, Mercosur countries take account of lists from a range of other countries, including the EU and the USA;

- **labelling:** labelling requirements are similar to those in the EU Directive (excluding those introduced by the 7th Amendment), including the use of INCI names[11]; and

- **safety and testing**: responsibility for cosmetics safety lies with manufacturers, who are expected to adopt GMP, similar to the EU position.

In general, the level of harmonisation between the regulatory framework for cosmetics in the Mercosur area and the EU Directive (up to the 6th Amendment) is high. Some differences remain, including requirements for pre-market registration. This may be a reflection of the in-market surveillance systems, which are less strong in Mercosur countries than in the EU. In these cases, pre-market registration provides an additional means of ensuring that manufacturers are meeting their obligations to ensure the safety of their products. Industry has indicated that it expects such requirements to be removed over time, as confidence grows in industry's ability to manage product safety.

Despite the proximity of the region to the USA, there appears to be no trend towards adopting US-style OTC categorisation for cosmetics. For instance, the negative lists include substances prohibited by the US FDA.

[11] This is not yet the official position in Brazil, where Portuguese translation is still required. This is expected to change in the near future with only INCI names being required. Brazil also requires labelling of an expiration date.

Table 6.1: Cosmetic Legislation in Mercosur Countries				
	Argentina	**Brazil**	**Paraguay**	**Uruguay**
Relevant Legislation	Resolution Number 155/98 (as modified) on Cosmetics, Personal Hygiene Products and Perfumes	Resolution RDC No. 79, of August 28, 2000 on Cosmetics, Personal Hygiene Products and Perfumes	Health Code, Article 280, Law No. 1119/97, Decree 17057, Decree 9973	Uruguayan Law No.15.443, 15.703, Decree 252/987 and Decree 95/90
Regulatory Enforcement	The competent authority responsible for granting cosmetic approval is ANMAT (National Administration of Pharmaceuticals, Food and Medical Technology) within the Argentinean Ministry of Health.	The competent authority responsible for Cosmetics is the General Office of Cosmetics within the Brazilian Ministry of Health. Product registration and surveillance is carried out by ANVISA (Agência Nacional de Vigilância Sanitária) - a public company which operates under contract to the Ministry of Health.	The competent authority responsible for Cosmetics is the Paraguayan Ministry of Health.	The competent authority responsible for Cosmetics is the Chemical and Pharmaceutical Division of the Ministry of Public Health.
Definition	Definition of cosmetics is identical to that in the EU Directive	Definition of cosmetics is identical to that in the EU Directive. There is no cosmetic-drug category. Cosmetic products are divided into four categories and two risk groups but similar regulations apply to each. However, for Category 2 products efficacy data are required to support claims made.	Definition of cosmetics is identical to that in the EU Directive. *Cosmetic Specialities* are cosmetics that make certain therapeutic and preventative claims.	Definition of cosmetics is identical to that in the EU Directive
Pre-market Requirements	Establishments that manufacture, import or sell cosmetics must be authorised by ANMAT. Cosmetic products which comply with the ANMAT regulations receive automatic approval and registration.	Establishments that manufacture cosmetics must be registered with ANVISA. There are also specific requirements for local manufacturers, importers and distributors. Notification of Category 1 cosmetic products is required, while product registration is required for Category 2 products.	Establishments that manufacture, distribute or store cosmetics must be registered with the Ministry of Health. Registration of all cosmetic products is also required.	Establishments that manufacture, distribute or store cosmetics must be licensed and registered with the Ministry of Public Health. Registration of all cosmetic products is also required.

Table 6.1: Cosmetic Legislation in Mercosur Countries				
	Argentina	**Brazil**	**Paraguay**	**Uruguay**
Controls over Ingredients	Ingredient lists are provided in ANMAT 1112/99 and are modelled after the lists of prohibited or restricted and positive lists in the EU Cosmetics Directive. There is also a list of 22 limited use ingredients.	Ingredient lists are provided in Resolution 79/00 (which adopts Mercosur Resolutions) and are modelled after the lists of prohibited or restricted and positive lists in the EU Cosmetics Directive. Brazil also recognises lists from the USA.	Permitted UV filters, permitted preservatives and ingredients that may not be used in cosmetic products are listed in the regulations.	Uruguay does not have any lists of approved, prohibited or restricted ingredients. In general, ingredients permitted in the US, EU and Japan are accepted.
Labelling and Warnings	Full ingredient listing (using INCI names) is required from January 2001.	Full ingredient listing is required. The nomenclature is not specified but names must appear in Portuguese. Expiration date must be labelled.	Ingredients should be identified by common or chemical names. INCI labelling is accepted.	
Testing and Safety	Cosmetics manufacturers are responsible for the safety of their products and are expected to adhere to GMP. GMP guidance is set out in ANMAT 1107/99 and follows the harmonised GMP guidelines of Mercosur Resolution 66/96.	Companies are responsible for the safety of their products and must retain data proving their safety and efficacy (under Resolution 79/00). GMP guidance is set out in Directive 348/97 and follow the harmonised GMP guidelines of Mercosur Resolution 66/96.	GMP is regulated according to GMC/Res/92/94 and GMC/Res/66/96. These regulations follow WHO GMPs.	Uruguay has adopted the harmonised MERCOSUR regulations (Resolution 66/96) for GMPs.

6.2.3 Harmonisation within Mercosur and Latin America

Harmonisation within Mercosur

Mercosur was originally set up with the goal of creating a common market/customs union between the participating countries on the basis of the various forms of economic cooperation which had been in place between Argentina and Brazil since the mid 1980s. In the field of cosmetics, significant steps and progress have been made in harmonising the regulations governing cosmetics in the Mercosur area. As noted above, harmonised standards relating to the definition of cosmetics, prohibited and restricted substances, labelling, manufacturers' responsibility for product safety and GMP requirements for cosmetics are already in place.

As Table 6.1 indicates, some countries within Mercosur are still in the process of adopting these harmonised standards fully into their national legislation. The harmonisation process was put on hold following Argentina's economic crisis but re-started at the end of 2003. Given the difficulties of achieving full harmonisation, the focus at present is on mutual recognition of registrations. Paraguay and Uruguay are indicated as still working towards harmonising and implementing the Mercosur regulations.

Harmonisation within Latin America

As well as within Mercosur, there are also moves for harmonisation with the **Andean States** (Bolivia, Columbia, Venezuela, Ecuador and Peru). Decision 516, adopted in July 2002, aims at harmonising national legislation on cosmetics. There are, however, implementation problems in relation to some specific issues. Bolivia is an associate member of Mercosur as well as an Andean State and may have a significant and/or strategic role to play in these harmonisations.

In Central America, too there are moves towards harmonisation. The **Central American Common Market** (which comprises Costa Rica, El Salvador, Honduras, Nicaragua and Guatemala) aims to publish harmonised legislation on cosmetic products in the near future.

Annual discussions have taken place between the competent authorities of Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Equator, El Salvador, Guatemala, Honduras, Mexico, Panama, Peru, Dominican Republic and Uruguay, with the goal of increasing alignment of regulatory frameworks between these countries.

Some of the key issues discussed at recent meetings include:

- **cosmetic labelling**, aimed at the adoption of INCI nomenclature;
- **information provision**, aimed at developing a common website to provide information to the public, with links to the pages of the other member countries, as well as to the competent authorities in force;

- **product safety, imports and market control**, focusing on harmonising the requirements, including technical information to be supplied by the manufacturers/importers of cosmetic products, as well as improved market surveillance of cosmetic products in the market; and

- **good manufacturing practice (GMP) guidelines**, aimed at harmonising the various guidelines currently present in the various countries.

It is possible that there could be further harmonisation of cosmetics legislation in the South America region with the EU Directive. For instance, Argentina is indicated to be very supportive (and has proposed the uptake) of certain key features of the EU model, such as the removal of product registration or manufacturer authorisation and prioritisation of in-market control. Discussions on this and other areas are expected to continue at the next meeting, scheduled for July 2004.

Trade negotiations involving all countries in the Americas (except Cuba) are also taking place. The outcome of these negotiations may have an impact on the future regulation of cosmetics in Latin America. **Mexico** is also a key player and, despite not belonging to regional agreements, has a clear influence on cosmetics regulations in the Caribbean region. Mexican legislation is similar to that of the EU, except for positive and negative lists.

6.3 The Regulatory Framework in the ASEAN Region

6.3.1 Regulation of Cosmetics

ASEAN is made up of ten Member Countries: Brunei Darussalam, Cambodia, Indonesia, Malaysia, Myanmar, Lao PDR, Philippines, Singapore, Thailand and Vietnam. It has a population of over 500 million and is therefore a major player in global trade.

The focus of ASEAN is on encouraging and improving economic and social growth among its Member Countries. It has taken significant steps recently towards harmonising cosmetic product regulatory frameworks in the region. The ASEAN harmonisation effort is embodied in the Agreement of the ASEAN Harmonised Cosmetic Regulatory Scheme which was recently signed by the ten ASEAN Member Countries and consists of two main measures. These are the ASEAN Cosmetic Directive and the ASEAN Mutual Recognition Arrangement of Product Registration Approvals. These measures will not come fully into force until 2008.

The Agreement has two main objectives:

- to enhance cooperation amongst Member States in ensuring the safety, quality and claimed benefits of all cosmetic products marketed in ASEAN; and
- to eliminate restrictions to trade of cosmetic products amongst Member States through harmonization of technical requirements, Mutual Recognition of Product Registration Approvals (MRA) and adoption of the ASEAN Cosmetic Directive.

The ASEAN cosmetic regulations share a number of key features:

- common definition of cosmetics and an illustrative list by category of cosmetic products;
- common ingredient listings and a handbook of cosmetic ingredients;
- common cosmetic labelling requirements;
- cosmetic claims guidelines;
- cosmetic product registration requirements;
- cosmetic import/export requirements; and
- guidelines for cosmetic GMP.

6.3.2 Similarities and Differences from Lead Legislation

The level of harmonisation between the ASEAN cosmetic regulations and the EU regulatory framework for cosmetics is high. Key features of the EU Cosmetics Directive which are contained in the ASEAN cosmetic regulations include:

- **definition of cosmetic products**: the ASEAN definition of cosmetics is essentially the same as the EU definition of cosmetics: *'any substance or preparation intended to be placed 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 exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition'*;

- **pre-market requirements**: there is no requirement under the ASEAN Cosmetics regulations for registration of cosmetic manufacturers or importers, or for pre-market approval for cosmetic products imported into or manufactured into the ASEAN region, similar to the EU position;

- **controls over ingredients**: Article 4.1 of the regulations states that Member States shall adopt the Cosmetic Ingredient Listings of the EU Cosmetic Directive 76/768/EEC including the latest amendments;

- **testing and safety**: as in the EU Cosmetics Directive, the ASEAN cosmetic regulations does not require information on the safety of cosmetic products to be submitted to the relevant authorities before a product is placed on the market. However, manufacturers/importers must retain information on the qualitative and quantitative composition of the product, specifications of the raw materials and finished product, manufacturing method, safety assessment by qualified person, existing data on any undesirable effects and supporting data for claims made for cosmetic products;

- Article 3 of the ASEAN regulations also states that cosmetic product placed on the market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the

product's presentation, its labelling, instructions for its use and disposal, warning statements as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the market; and

- an ASEAN Cosmetic Committee (ACC) will be set up, which will establish an ASEAN Cosmetic Scientific Body (ACSB) to assist in reviewing the ingredient lists, technical and safety issues. The ACSB is expected to consist of representatives from the regulatory authorities, the industry and academia and its role will be similar to that of the SCCNFP in the EU.

6.3.3 Harmonisation within ASEAN

The implementation of the common minimum requirements under the ASEAN Harmonised Cosmetic Regulatory Scheme is expected to begin in 2004 for the countries who are ready for the first phase. Phase I concerns the ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetics, which specifies requirements and procedures for the implementation of the mutual recognition of product registration approvals for cosmetics amongst the Member Countries.

Phase II, which involves the implementation of the ASEAN Cosmetic regulations is expected to be completed by 2008. Between 2004 and 2008, the required infrastructure (such as the ASEAN Cosmetic Good Manufacturing Practice (CGMP), the ASEAN Scientific Cosmetic Body (ASCB) and the Post Marketing Surveillance/Safety Evaluation) for the full and successful implementation of the regulations will be developed.

A joint association for the cosmetics industry in ASEAN has also been set up, modelled on Colipa (the European association).

Until implementation is complete, differences between the regulatory frameworks for cosmetics in ASEAN Member Countries will remain in place.

6.4 Regulatory Frameworks in Other Third Countries

6.4.1 Influence of the EU Model on Regulatory Frameworks

No country outside the European Economic Area and EFTA has fully implemented the provisions of the EU Cosmetics Directive into its national or regional legislation. One exception may be the South African cosmetic self-regulation proposed by the South African Cosmetics Industry Association (CTFA-SA) and endorsed by the local authorities, which is very similar to the EU Directive (Colipa, 2004b). Equally, as discussed in the previous sections, the Mercosur, Andean Pact and ASEAN regions have used the framework of the EU Directive in developing their harmonised regulatory approaches.

Other countries have reproduced some features of the EU Cosmetics Directive, particularly the definition of cosmetics and/or the lists of regulated ingredients. These include Japan, Canada (discussed in Section 3), China (discussed above), Algeria, India, Israel, Morocco and Saudi Arabia.

In general, the features of the EU Cosmetics Directive that are adopted in other countries/regions include:

- the definition of a cosmetic under the EU Cosmetics Directive has been adopted by around 50 countries in total; relatively few countries (most importantly Korea) have adopted categories similar to the Japanese quasi-drug category or have classified products as OTC drugs, as in the USA and Canada;

- requirement for cosmetic products to be safe and manufacturers responsibility for the safety of the product;

- regulation of substances based on a negative list of prohibited ingredients, a restricted list of ingredients subject to restrictions and positive list of UV filters, preservatives, colouring agents, etc. At present, around 30 countries are thought to have adopted the EU lists (though often with some changes); and

- responsibility of the competent authority to put in place in-market surveillance systems to monitor compliance.

Other important features of the EU Cosmetics Directive are, however, not usually emulated in other regions or countries known to have adopted other parts of the legislation. These features include:

- the EU notification system which is usually replaced by a registration procedure; and

- EU labelling rules, which are substituted by regulations requiring companies to 'customize' the labeling of products for specific local markets.

6.4.2 Regulatory Issues in Other Third Countries

Introduction

During discussions with stakeholders, a number of issues concerning the regulatory frameworks in particular countries have been identified. These issues are set out briefly below for:

- Russia;
- Ukraine;
- Korea;
- Taiwan; and
- Australia.

Russia

Current Russian legislation imposes strict safety requirements on imported cosmetic products. All imported products must have a safety certificate issued by the appropriate local certification centre. The procedure can take considerable time to complete and involves microbiological, chemical, toxicological and clinical laboratory tests, which can be costly. Companies are required to submit samples of products to be imported, along with data on ingredients, applications and the country of origin. Only products certified as tested under German and Swiss quality procedures are exempt from this requirement.

Labelling requirements in Russia are similar to those in the major markets, including information on ingredients, any potentially harmful substances, instructions for use, expiration dates or limits to usability and information on possible reactions.

As noted above, significant revisions to Russian cosmetics regulations are currently being developed. These are expected to lead to greater harmonisation with the EU model.

Ukraine

Procedures for import of cosmetics into Ukraine were considerably simplified in 2001 and the requirement for licensing of imported cosmetic products was removed. However, pre-market hygiene approval from the Ministry of Health is required to import cosmetic products into Ukraine and certain hair products are also subject to certification.

Korea

Korean cosmetics regulations also differ considerably from the main regulatory models and concern has been expressed by the industry that they may act as a barrier to trade.

A new cosmetics law (Cosmetics Law No. 6025 of 1999) was adopted in July 2000 that separated the regulation of cosmetics and pharmaceuticals. The regulations distinguish between ordinary cosmetics and functional cosmetics; the latter are products that enable whitening of the skin, alleviate or diminish wrinkles, promote even tanning or protect the skin from ultra-violet rays. Functional cosmetics are subject to pre-market screening and registration and special labelling provisions.

The aim of the change was to simplify regulation, but in practice only a handful of products were registered and most foreign companies found registration very difficult. Changes to regulations on functional cosmetics were notified in January 2003, in response to industry concern about their impacts on markets and innovation but, according to industry, the changes have had little effect.

There are also concerns about testing requirements, including efficacy testing of certain sunscreens and a requirement to test cosmetic products for heavy metals.

Taiwan

Cosmetics in Taiwan are regulated under the Law for the Control of Cosmetic Hygiene introduced in 1972 and amended in 1999. Cosmetic products are divided into general cosmetics and medicated cosmetics; this classification is based on the claims made and the ingredients in the product. Medicated cosmetics are 'cosmetics containing medicated ingredients, but no more than the maximum allowed under the DOH (Department of Health) Standards'. Examples of medicated cosmetics include products containing hormones, certain preservatives, sunscreens, hair dyes or vitamins, permanent-wave solutions, whitening products, anti-acne products, deodorants and anti-perspirants. Products making anti-ageing and other therapeutic claims are categorised as drugs. All medicated cosmetics must be registered and approved prior to manufacture or importation; general cosmetics do not require product registration.

The regulatory framework in Taiwan is not based on any major market model and no harmonisation with EU model is planned. Indications from industry suggest it is becoming more different from the EU model.

Australia

Products in Australia are determined to be either cosmetic or therapeutic goods based on the proposed use and composition of the product. Drugs and cosmetics are divided into four categories in Australia:

Registered Therapeutic Goods (RTGs): these are pharmaceutical products that undergo a full evaluation process. Ingredients used in registered therapeutic goods must be on the Australian Register of Therapeutic Goods (ARTG) and registered therapeutic goods must be assigned an AUST R number on the ARTG;

Listable Therapeutic Goods (LTGs): these are products which present a lower safety risk than RTGs and include vitamins, minerals and sunscreens (with an SPF4 greater than or equal to 4, or less if containing human or animal tissue). Only ingredients previously approved as safe for use in LTGs may be used. LTGs must be listed on the ARTG and must be assigned an AUST L number;

Exempt Therapeutic Goods: these products are considered to be therapeutic goods and as such, can make therapeutic claims in accordance with the regulations. These products include anti-perspirants (if the active ingredient is Al, Zn and Zr salts), anti-acne cleansers, anti-dandruff products, medicated insect repellents, fluoride toothpaste (below 1,000 ppm fluoride) and sunscreens below SPF4 (not containing human or animal tissue). These products are exempt from manufacturing licensing and product registration requirements; and

Excluded Goods (including cosmetics): these are products that are applied to the skin and have a non-therapeutic primary purpose. These products are allowed to make certain therapeutic claims specified in the regulations and include lipstick and facial make-up

with no sunscreens, deodorants and depilatories for use on skin, nail hardeners and nail biting detergents, hair bleaches, dyes, colourants and perms .

There are no suggestions that cosmetic regulations in Australia are becoming more similar or different from the EU model.

PART IV:

NEW DEVELOPMENTS/TRENDS IN COSMETICS LEGISLATION

7. INNOVATION AND REGULATORY DEVELOPMENT

7.1 Significance of New Developments and Trends

The previous sections of the Report describe the current regulatory frameworks for cosmetic products in the main and emerging markets and the impacts of differences in regulatory frameworks on the cosmetics industry and other stakeholders. However, the cosmetics industry is a dynamic industry, characterised by innovation and a high rate of product development. It is therefore important to consider the impact of regulatory frameworks on recent or foreseeable technological developments.

Equally, the regulatory frameworks applicable to cosmetics are not static but are subject to continuous development in response to emerging scientific knowledge and the developing concerns of consumers and other stakeholders. Some of these changes will reduce the differences between the regulatory frameworks applicable to cosmetics world-wide. Other changes may have the effect of increasing the differences, with implications for both the cosmetics industry and other stakeholders.

This section of the Report:

- discusses the main innovations taking place in the cosmetics industry;
- assesses the impacts of current regulatory frameworks on innovation;
- identifies developments in legislation at the European level and trends towards global harmonisation; and
- assesses the implications of these future developments for innovation in the cosmetics sector.

7.2 Innovation in Cosmetics and Market Growth

The market for cosmetics world-wide has continued to grow over the period 1998-2002, despite the difficult economic climate during recent years. Over this period, the Western European market (the EU-15 plus Norway and Switzerland) has grown by an average of around 5% per year to increase from €47 billion in 1998 to €57 billion in 2002. The market in the USA has also grown throughout this period, by a slightly lower percentage, whilst the market in Japan has remained flat or even contracted (in 1998 and 2000) in line with economic conditions (Heerink, 2003). The cosmetics market in the EU-15 (€33.2 billion at ex-factory prices in 2002) is larger than the US market (€32.6 billion in 2002) and more than twice the size of that in Japan (€14 billion in 2002).

Rates of growth, and market share, vary between the different cosmetics product categories. Table 7.1 shows rates of growth and market shares across product categories for cosmetic products in Western Europe (EU-15 plus Norway and Switzerland) in 2002.

Table 7.1: Market Share and Growth by Product Category in Western Europe, 2003		
Product Category	**Market Share (%)**	**Growth (%)**
Hair Care	25.1	+3.6
Toiletries	24.8	+3.0
Skin Care	23.5	+6.0
Fragrances and Perfumes	14.8	+0.5
Decorative Cosmetics	11.9	+2.7
Source: Colipa (2004)		

A considerable proportion of the growth in cosmetics markets is driven by innovation, with several thousand new or improved products placed on the market each year. Work by RPA (2003) has indicated that, on average, major cosmetics companies replace or reformulate around 25% of their products each year. Many cosmetic and toiletry products have a lifetime of five years or less, though certain brands can have a much longer lifetime (over 100 years in the case of some perfumes) and SMEs tend to replace or reformulate products less frequently. The industry believes that innovation is essential to maintain global competitiveness, improve performance, safety and the environmental impact of products. The main growth areas within the product categories are outlined in Table 7.2.

Table 7.2: Main Growth Areas within Product Categories	
Product Category	**Main Growth Areas**
Hair Care	Tailor-made products (shampoos and conditioners for a range of hair types); 'casual' look styling products; colouring products.
Toiletries	Whitening toothpaste; mouthwash; shaving foams for women/sensitive skins; new formulations and fragrances in shower gels; compact deodorants and deodorant towels; liquid hand soap.
Skin Care	Anti-wrinkle and anti-ageing products (for face and body); wet and dry cleansing towels; sunscreen products with a higher SPF.
Fragrances and Perfumes	More exclusive brands; new fragrances and brands.
Decorative Cosmetics	Single application, long lasting products; innovative packaging and application.
Source: Colipa (2001)	

A number of key areas of innovation have been identified (Colipa, 2004b); these include:

- 'added value' products, such as moisturisers with anti-ageing properties, styling products for damaged hair;
- products focused on particular consumers or designed to treat a specific problem (e.g. different toothpaste types (including whiteners), cosmetic lines for teenagers, facial care ranges for men, ethnic products);
- 'caring' products, such as moisturisers, shampoos, deodorants and soaps to take special care of skin and hair; and

- greater convenience, products with special packaging or novel means of application (e.g. small, single usage items).

In future, further innovations may arise from:

- on-going advanced research activities on the composition of skin and hair and the way in which they function, which are already leading to innovative and more efficient molecules; and

- use of genetic techniques. Industry sources indicate, however, that such technologies are unlikely to be used in cosmetics in the near future.

7.3 Types of Innovation Affected by Regulatory Frameworks

7.3.1 Introduction

Different types of innovation are affected in different ways by the diverging regulatory frameworks at international level, with consequent impacts for the innovating companies. In broad terms, innovations in cosmetics can be divided into three broad types. These are:

- innovations in delivery mechanisms;
- innovations in ingredients and product composition; and
- innovations in marketing and presentation of products.

The impacts of regulatory frameworks on each of these types of innovation are discussed below.

7.3.2 Innovation in Delivery Mechanisms

Innovations in delivery mechanisms have been a major source of market growth for the cosmetics sector in recent years. They include, for example, shaving foams in gel form and cosmetic wipes, as well as the use of nanotechnology to deliver vitamins E and C in anti-ageing creams into the upper layers of the epidermis.

These products use the same ingredients as traditional products, but are delivered in a different way. Regulatory frameworks are generally not a significant issue for such types of innovation, as the same requirements generally apply to the product however it is delivered (although if such innovation results in different claims being made for products, this could affect the way in which a product is regulated). Impacts would only arise if delivery mechanisms were used that go beyond those specified in the definition of cosmetics, which generally exclude delivery through inhalation, injection or ingestion. There may be some issues in future, however, should delivery mechanisms enable penetration of ingredients beyond the first layer of the skin.

7.3.3 Innovation in Ingredients and Product Composition

Innovations in ingredients and product composition involve improvement of the properties of existing products, such as more effective sun products, and addition of further functions, such as anti-ageing face creams. This is achieved through the addition of new ingredients or different combinations of existing ingredients. Current regulatory frameworks can inhibit this process, and thus act as a barrier to innovation, through:

- differences in the ingredients permitted and prohibited for use between different markets (i.e. different positive and negative lists). This means that new formulations based on existing ingredients cannot be launched universally, especially where a product is categorised as a drug or quasi-drug where approval is required for all ingredient changes (even if the ingredient can be freely used in cosmetics);

- differences in the information requested and the time taken for the approval of new ingredients. This can significantly delay product introduction and increase costs. Again, time-scales and information requirements are greatest where products are categorised as drugs or quasi-drugs. The problem is exacerbated by the lack of mutual recognition of safety data; and

- differences in labelling requirements can act as a barrier to innovation by increasing the costs, or even preventing the launch, of new product launches. The impact is greatest where there is a positive list of claims and only claims included in the list can be used (this applies most often where a product is categorised as a drug or quasi-drug).

The impacts of these barriers for new formulations of existing ingredients and for products with new ingredients are discussed further below.

New Formulations of Existing Ingredients

As Parts II and III of the Report show, significant differences remain between the positive and negative lists of ingredients used for cosmetic products in the EU and other markets. Ingredients accepted for use in the EU are widely considered to be safe, as demonstrated by the adoption of EU lists in a number of markets. However, as the case studies in Section 4 demonstrate, some regulators require evidence of use of an ingredient within their market before approval for use is granted. In others, the process of approval is not transparent or is costly and time-consuming, so that approval for certain ingredients has not been sought. There are also differences in the underlying approach to evaluating safety, the level of data required and the way in which the precautionary principle is implemented. Again, the EU approach is generally seen by the stakeholders consulted for this study as being clear, open and offering a high degree of consumer protection.

These differences create barriers to the development of new 'global products' and increase the costs of product innovation. For example:

- differences in the lists of UV filters approved for use in the main markets (illustrated in Case Study 1 in Section 4) mean that new formulations have to be modified for different markets, companies cannot rely on a global product. This increases the costs of innovation and reduces the potential market size. Inability to use new filters may also restrict the efficacy of the product;

- new formulations of whitening products must use different active ingredients in the USA and Japan because of the limited number of permitted active ingredients. (In the USA only one active ingredient is permitted; this is banned in other markets on safety grounds). This has resulted in some innovative products not being placed on the market in those countries; and

- replacement of preservatives that are not accepted in Japan, even though they have been assessed as safe under the EU Cosmetics Directive, can add significant costs (in the region of €1 - €3 million) to product development.

The impacts are greatest where products are categorised as quasi-drugs or OTC drugs in certain markets, as such categorisation poses further restrictions on changes to formulations. In Japan, for example, ingredients that are permitted for use in cosmetics still require approval before they can be used in quasi-drugs. In the US, OTC monographs specify the ingredients that can be included in particular OTC products; changes cannot be introduced without seeking new drug approval.

Products with New Ingredients

Where innovative products contain new ingredients, barriers to innovation may arise because the new ingredients require approval. This may be because they need to be added to a positive list for cosmetics ingredients (for example, UV filters) or because the product is categorised as an OTC or quasi-drug.

The time taken to approve new ingredients varies between markets; Case Study 1 (in Part II) illustrates the variations in time taken for approval of new UV filters. The majority of time is taken in generating the safety data required to be submitted by the regulatory authorities; this ranges from two to three years in the EU and five to seven years in the USA. Following submission of the file, the time taken for approval is generally one year or less, except in Japan and the USA.

In the USA, the main problem arises where OTC monographs are in place as these have the effect of 'freezing' a certain set of permitted ingredients. New ingredients need to be approved through the New Drug Approval Process. A particular issue has arisen with UV filters, as well as anti-dandruff shampoos

and anti-caries toothpastes (additional fluorides cannot be introduced). The introduction of Time and Extent Applications (TEA) in 2001 was designed to ease the problem – ingredients used in products marketed for at least five years outside the USA can be introduced for products subject to OTC monographs without New Drug Approval. In practice, though, no ingredients have yet been approved under TEA and the process of seeking TEA approval is nearly as demanding as that for a new drug. There are particular problems with UV filters as the relevant OTC monograph is currently being revised; one company indicated that it has been seeking approval for a new UV filter for 30 years.

Some delays in marketing products with innovative ingredients are accepted as inevitable by the industry, because of the need to ensure the safety of the ingredients and the products containing them. In general, the time taken by authorities to approve ingredients after the submission of files is seen as reasonable. The greatest barriers to innovation arise, however, from the differences in information requirements of the different regulatory authorities (also illustrated in Case Study 1). This can add significantly to the costs of approval for new ingredients. In the USA, there is also the issue that existing ingredients were included in monographs on the basis of limited information (some times prepared as much as 25 years ago). Much more detailed data are now requested for new ingredients, because of advances in knowledge, increasing the costs of approval and providing a further barrier to innovation.

The approval process also gives rise to competition concerns amongst some companies. In the US, for example, all discussion with the FDA on approval of new ingredients is public, so that competitor companies can become involved. Companies that have spent time and money obtaining approval for their ingredients could use this opportunity to try to prevent approval of new ingredients by their competitors, acting as a barrier to innovation.

7.3.4 Innovations in Marketing and Presentation of Products

Innovations in the perception and marketing of products, emphasising their contribution to a feeling of 'well-being' as well as an improved appearance, are increasingly important to the cosmetics sector. This is reflected not only in the marketing of cosmetics, but also in the development of new product lines, such as aromacosmetics. It also forms the basis of a number of voluntary industry programmes focusing on hospital patients. In the USA and UK, the 'Look Good – Feel Better' programmes provide cosmetics advice to cancer patients, raising self-esteem and increasing confidence. In Finland, similar programmes have operated in a range of hospitals, including a psychiatric hospital.

These programmes, along with scientific research in Japan and Europe, have illustrated the link between the physical application of products to the skin and the user's mental state. At the same time, improvements in science are showing that, for example, the simple action of rubbing a cream onto the skin

surface can induce physiological changes in lower layers. This understanding is not generally reflected in the definition of cosmetics in existing regulatory frameworks. These definitions instead reflect the view that the external parts of the body to which cosmetics are applied (the skin), together with teeth and oral mucous membranes, are a separate external envelope, which is not linked to internal parts of the body or with the mind.

The definition of cosmetics in the EU Directive, as described in Part II of the Report, identifies six intended functions for which cosmetics applied to the body are 'mainly or exclusively' intended (similar definitions are used in other markets). These are:

- cleaning the parts of the body to which they are applied;
- perfuming them;
- changing their appearance;
- correcting their body odours;
- protecting them; and
- keeping them in good condition.

The expression "*mainly or exclusively*" in the EU Directive shows that the definition of cosmetics covers not only products intended exclusively for the functions listed above but also products with other functions, provided that one of these six functions is predominant. Where the promotion of well-being is presented as the main purpose of a product, though, this could lead to uncertainty about its categorisation and act as a barrier to innovation. For this reason, China is considering a new definition of cosmetics that focuses on their purposes in promoting well-being and self-esteem.

7.4 Impact of the EU Regulatory Framework on Innovation

7.4.1 Introduction

Consultation carried out for this study indicated that most stakeholders consider that the current EU regulatory framework has enabled innovation, rather than acting as a barrier. This is particularly the case when compared with regulatory frameworks in the USA and (at least until deregulation in 2001) to Japan.

However, a number of recently introduced changes to the EU regulatory framework could have the potential to act as a barrier to innovation in future. The potential impacts of amendments to the Cosmetics Directive and the Medicinal Products Directive, the Biocides Directive and REACH are discussed below.

7.4.2 Amendments to the Cosmetics Directive

The EU Cosmetics Directive has recently been the subject of a review under the SLIM (Simpler Legislation for the Internal Market) process. This review covered the Directive up to and including the 6th Amendment, and will feed into future regulatory development. The key findings of the SLIM review are summarised in Table 7.3; the review made a number of detailed recommendations of how these findings could be addressed.

Table 7.3: Key Findings of the SLIM Review of the EU Cosmetics Directive

- The protection of consumers and the provision of guidance on the composition, manufacturing process, safety and control of products, their packaging and labelling and market surveillance should remain the main objective of the legislation.
- The person placing a product on the market is totally responsible for ensuring its safety and compliance. This should be underlined.
- The principle that safety is required for all product categories, taking into account their normal or reasonably foreseeable conditions for use should be clearly specified.
- Introduction of a glossary, with clear definitions of terms and words, would overcome differences in interpretation of the text.
- Administrative co-operation, which enables free circulation of cosmetics products, does not operate entirely satisfactorily.
- Most of the provisions in the current Directive are considered necessary. However, imprecise definitions in the text hamper free circulation as these are open to different interpretation by national authorities. Member States should be encouraged to share a common approach.

The SLIM review did not cover the 7th Amendment to the Cosmetics Directive (Directive 2003/15/EC), which was adopted on 29 February 2003 and published in the OJ on 11 March 2003, as the SLIM exercise was concluded prior to the amendment of the cosmetics directive.. The main provisions of the 7th Amendment are:

- a **testing ban** preventing cosmetics products and ingredients for cosmetics products being tested on animals within the EU. The deadline for implementation of the ban on tests for finished products is 11 September 2004. The ban on tests for ingredients takes effect according to progress with the timetable for the development of alternatives and not later than 11 March 2009;

- a **marketing ban** on cosmetics products tested on animals, and on products containing ingredients tested on animals, whether testing was carried out within the EU or elsewhere. The marketing ban will come into effect according to progress with the timetable for the phasing out of animal tests and their replacement by alternatives, and not later than the 11 March 2009. However, for three specific types of tests, the marketing ban deadline may be 11 March 2013 if there are no alternatives under consideration, unless this date is postponed;

- a strict prohibition on the use of **substances with carcinogenic, mutagenic and reprotoxic properties (CMRs)**, with the potential for risk

assessment-based exemptions for Category 3 CMRs on a case-by-case basis;

- a requirement to make available to the public upon request a range of **product information**, covering product composition and related adverse effects;

- a requirement for companies to include **data on animal testing** on the product ingredients in the product information available to competent authorities; and

- a requirement to **label** the "Period After Opening" for products with a shelf life of more than 30 months after which a product can be used safely as well as the presence of 26 fragrance allergens.

The cosmetics industry, in the EU and elsewhere, has expressed concerns about the impact of the 7th Amendment on innovation, particularly in relation to the testing and marketing bans. The timetable for development of alternatives to animal tests under the 7th Amendment is challenging, and there are concerns that it may not be met despite the major efforts of the industry, supported by the Commission, to accelerate progress. For the majority of end-points, the 7th Amendment does not allow for an extension of the use of animal testing if alternative tests are not available in time. If the delay meant that no acceptable tests were available for certain end-points, the implications for innovation could be significant as follows:

- the use of new colourants, preservatives and UV filters could be prevented, as these require specific safety tests to be carried out before they are approved for use by the Commission based on an SCCNFP opinion;

- the use of other new ingredients might be limited, as the unavailability of tests could mean that manufacturers feel unable to confirm the safety of products in line with the requirements of the Cosmetics Directive;

- the use of existing ingredients might also be compromised, if requirements for safety testing relating to end-points for which no alternative tests were available were imposed by national or European authorities in response to health concerns; and

- it is not clear how far the use of existing ingredients might be compromised if animal tests were carried out on them for other purposes, for example under the Existing Substances Regulation (No. 793/93/EEC) or REACH (see Section 2.3.5).

7.4.3 Amendment to the Medicinal Products Directive

Responses from industry consultees indicate that the categorisation of a wide range of products as cosmetics, rather than OTC or quasi-drugs, enhances innovation. Having clarity about the borderline between cosmetics and medicines in the EU is therefore an important contributor to innovation.

The recent amendment to the Medicinal Products Directive (2001/83/EC as amended in 2004) introduced a revised definition of medicinal products, '*any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be used in or administered to human beings or animals with a view to making a medicinal diagnosis or to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action*'.

The revised Directive confirms that products can only be categorised as either a medicinal product or a cosmetic, not both, and that categorisation should take full account of all the characteristics of the product. However, when doubts remain, the product will be considered as a medicinal product.

Interpretation of the definition could vary between Member States, which already have different approaches. Some, such as Italy and Belgium, ban claims of preventive effects for cosmetics (Belgium allows only limited claims in general) while others, such as France, have no such limitations. Such ingredients can be used in Italy and Spain, though, provided their concentration is lower in the cosmetic (for example, Vitamin E). However, some ingredients have been approved by the SCCNFP for use in cosmetics at the same concentration as used in pharmaceuticals in some countries. Uncertainty over such differences in interpretation could restrict the market for new products and thus act as a barrier to innovation.

7.4.4 Biocidal Products Directive

The Biocidal Products Directive (EC, 1998) is intended specifically to exclude from its scope products regulated under other EU measures, including the Cosmetics Directive. However, guidance on the borderline between the Biocides and Cosmetics Directives has not yet been finalised and some questions remain regarding products that combine UV filters with insect repellents, and regarding preservatives and deodorants recognised to have anti-microbial effects.

The main significance of the Biocides Directive, however, is as an indicator of the potential effects of REACH, which adopts a similar approach for registration (see Section 7.4.5). The requirements for registration under the Biocides Directive appear likely to result in a significant reduction in the number of products on the market. Some respondents have indicated that, before the Directive's adoption, there were 800-1,000 substances, whereas

now there are only 350 and each month more are withdrawn from the registration process.

7.4.5 REACH

The cosmetics industry is a significant downstream user of substances and preparations produced by the chemical industry. The European Commission's Proposed Regulation on the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **CH**emicals (REACH) (EC, 2003b) could therefore have significant implications for the sector, through:

- increased prices for chemical inputs as manufacturers seek to recover the costs of REACH;
- loss of availability of chemical products as manufacturers rationalise their product range and fail to support certain substances through REACH; and
- impacts arising from the public availability of information.

These factors could affect the costs of developing new products and the market for them. The loss of ingredients, through failure of manufacturers to support registration, could also affect the continued production of existing cosmetic products.

In addition, there are potential incompatibilities with the 7th Amendment to the Cosmetics Directive. For instance, REACH will require testing to be carried out on a wide range of substances, including animal testing, while the Cosmetics Directive may prohibit them. The result could be a further barrier to innovation through the use of new ingredients and could result in the loss of existing ingredients.

8. TRENDS IN ALIGNMENT OF REGULATORY FRAMEWORKS

8.1 Current Extent of Alignment

8.1.1 Introduction

Parts II and III of this Report describe the similarities and differences in regulatory frameworks between different markets for cosmetics. Part II also sets out the impacts of differences in regulatory frameworks for the various stakeholders. For manufacturers in particular, differences in regulatory frameworks can impose significant financial and other costs. As Section 2 describes, differences in regulatory frameworks can also introduce barriers to innovation.

Fewer differences between regulatory frameworks would reduce these costs and barriers to innovation. However, it is unrealistic to assume that complete harmonisation of legislation is possible, certainly not in the short or medium term. There is, however, considerable potential for further alignment of regulatory frameworks that stops short of full harmonisation. Barriers to further alignment, current activities to encourage alignment and suggested further measures are discussed in this Section.

8.1.2 Barriers to Alignment

As Parts II and III demonstrate, current regulatory frameworks have developed over a considerable period of time, and reflect cultural differences between markets as well as legislative traditions. Countries with OTC/quasi-drug categories, for example, are reluctant to move towards a wider definition of cosmetics. Japan has only recently undertaken a major deregulation exercise on cosmetics, in which the quasi-drug category was retained. It would be unrealistic to expect further widening of the definition of cosmetics in the short term. In Canada, a major review of health protection legislation is under way (under the legislative renewal programme) that could lead to changes in cosmetics regulation in the longer term, but a change in the definition of cosmetics could have wide implications.

In the USA, the definition of cosmetics has remained unchanged since it was first introduced in 1938 and there seems to be no enthusiasm, amongst industry or competent authorities, to make such a change. A recent initiative in California to tie state-level cosmetics legislation to the EU Directive was opposed by industry, on the basis that it would be inconsistent with the existing USA regulatory framework.

The responses of industry and non-EU governments to the consultation carried out for this study indicate that the 7th Amendment to the Cosmetics Directive

is seen as a potentially significant barrier to international harmonisation of cosmetics regulations and to innovation within the industry.

It is apparent that the requirements of the 7th Amendment, particularly in relation to animal testing, are not yet well understood internationally. Nevertheless, a number of concerns were voiced by manufacturers and competent authorities outside the EU on its potential impacts, even in countries where the EU regulatory model was generally seen as positive. These included:

- the requirements on durability labelling and labelling of fragrance allergens are seen as a barrier to harmonisation in both the USA and Japan. They will require the development of different labels for the EU market, increasing costs for both new and existing products;

- the prohibition on the use of CMRs is seen as a move away from a risk-based approach to a hazard-based approach; and

- incompatibility of the restrictions on animal testing with practices elsewhere. This is seen as potentially the greatest barrier to harmonisation and innovation.

In China, there is still a requirement for finished products to be tested on animals. Elsewhere, animal testing is seen as the most reliable means of evaluating the safety of cosmetics and none of the markets covered by the study are planning to restrict the use of animal tests. Alternative tests will only be acceptable if they can guarantee an equivalent level of safety. In most countries, animal testing is not a political issue and it is unlikely that resources will be invested into the development, validation or implementation of alternatives.

At best, this may mean a delay between the adoption of alternative tests in the EU and their acceptance elsewhere. During this period, companies might delay the introduction of new ingredients requiring testing into their products, thus limiting the available information. At worst, if other markets choose not to accept alternative test methods at all, the impacts on innovation could be very significant. The fact that the 7th Amendment prohibits the use of ingredients tested on animals anywhere in the world would mean that new ingredients developed and tested outside the EU could not be used in products within the EU. Similarly, ingredients tested using alternatives in the EU, and used in EU products, could not be used in products outside the EU, because they would need to be tested on animals and this would make them unavailable for use within the EU. This could result in two parallel markets for cosmetic products, with innovation in one market not transferable to the other. The reduced size of the market for new products is likely to act as a considerable barrier to innovation.

8.2 Progress Towards Alignment

As Parts II and III of this Report indicate, no country or region outside Europe has fully incorporated the provisions of the Cosmetics Directive into its national or regional legislation. A number of regions working towards harmonisation of cosmetics legislation have, however, used the EU Directive as a model, in particular:

- Mercosur;
- Comunidad Andina (Andean Pact); and
- ASEAN.

Once the process of harmonisation is complete, this could bring significant benefits for innovation by increasing the size of the market for 'global' products. At present, though, harmonisation is incomplete and barriers to innovation are still in place. For example, although the ASEAN countries have embarked on a harmonisation process, this is not yet fully in place (the deadline for its implementation is 2008). Particular issues remain with the move from pre-market to in-market control and differences in the acceptance of claims. In fact, several ASEAN countries (e.g. Malaysia, Indonesia and the Philippines) have developed more complex national legislation, in parallel with the harmonisation process, as the importance of legislation in ensuring product safety has been recognised. In practice, this has made it more difficult to market products in many of these countries than used to be the case when national legislation was more limited.

In South and Latin America there is a similar phenomenon, although to a lesser extent, with the harmonisation processes sometimes leading to the increased complexity of regulations in some countries. In some cases, the harmonised systems do not appear to be working fully. For example, in the Andean Pact area, although there is mutual recognition of notifications, some companies have indicated that it takes longer to activate the mutual recognition process than to carry out the notification process in every country.

Other countries have reproduced some features set out in the EU Cosmetics Directive in their national legislation, mainly the definition of the cosmetic product and/or the lists of regulated ingredients. The two most important markets in which this has taken place are Japan and Canada. The changes to Japanese regulations, which came into force in 2001, were seen as particularly significant by respondents, significantly increasing the market available for global products and encouraging greater innovation in products on the Japanese market. Indeed, the rapid rate of innovation of cosmetic products, which posed increasing problems for the authorities in keeping pace with requests for product approval, was a major factor leading to the Japanese cosmetics deregulation process.

Some respondents noted that distinction should also be made between adopting the wording of the EU Cosmetics Directive and harmonisation of

practical application. In particular, this relates to manufacturers' responsibility for safety. Article 2 of the EU Cosmetics Directive states that products placed on the market in the EU must be safe, but does not specifically state that manufacturers are responsible for achieving this. The SLIM review, described in Section 7.4.2, recommends that this point is clarified in future regulations. Article 3, meanwhile, places the responsibility on Member States to ensure that only conforming products are placed on the market.

If there is no effective market surveillance system in place, public health risks might arise, in particular in countries without effective administrative arrangements. How can the authorities ensure the safety of products without knowing anything about them? This is the reason why some countries, including Brazil, have retained a system of product registration. They believe that this ensures that responsibility for safety is shared between the authorities and the manufacturers. Similar conclusions are said to have been drawn in Russia and China.

Nevertheless, such problems are probably only temporary and, in the longer term, regional harmonisation along the EU model is likely to bring significant benefits for innovation.

8.3 Activities to Encourage Alignment

8.3.1 Measures to Enhance Alignment and Innovation

Organisations consulted for the study, including industry and competent authorities in the EU and elsewhere, suggested a number of measures that could be adopted to further align cosmetics legislation, encourage innovation and enhance market growth. Some of these measures were recognised as more realistic than others. The measures suggested include:

- a common definition of cosmetics;
- common positive lists of ingredients;
- common approaches to safety testing;
- greater alignment in labelling and packaging rules; and
- increased use of international guidelines.

Common Definition of Cosmetics

Industry would welcome increased harmonisation of the definition of cosmetics, in line with the definition in the EU Cosmetics Directive. This wide definition, combined with clear guidance on safety, combines flexibility with a high level of consumer protection and has gained the confidence of regulators and consumers as well as the industry. The procedures associated with narrow definitions of cosmetics, with many products categorised as OTC or quasi-drugs, are seen as imposing restrictions unnecessary for consumer

safety, increasing costs and limiting innovation. Industry recognises that definitions are unlikely to be changed in the USA and Japan, primarily for cultural and historic reasons. Simplified (and transparent) procedures for registration of OTC/quasi-drugs would help to reduce barriers to trade.

In parallel, an equally clear definition of pharmaceuticals should be encouraged, with a clear boundary between the cosmetics and pharmaceuticals. There also needs to be effective co-ordination with other legislation affecting cosmetics, including legislation applicable to ingredients (such as new substance notification in the EU and Canada, the Biocides Directive and REACH proposals in the EU).

Recognition of Producer Responsibility

Under the wider definition of cosmetics, there should be explicit recognition of producer responsibility for product safety (as recommended by the SLIM review of the EU Cosmetics Directive). This not only places responsibility for safety on those most qualified to meet it, it also reduces unnecessary burdens on competent authorities in carrying our pre-market approval.

Such an approach needs to be supported, though, by effective in-market surveillance in order to give confidence to consumers that regulatory requirements are being met. This is a particular concern in emerging markets. Development of guidance on in-market surveillance, together with the necessary training for enforcement authorities, would assist in ensuring consistency.

Industry can also assist in supporting consumer confidence in producer responsibility, by supporting effective enforcement and by interacting in an open way with regulators, consumers or other stakeholders when concerns about the safety of products are raised.

Common Positive Lists of Ingredients

The use of common positive lists of ingredients would be welcomed by industry. If this is not possible, ingredients included in the positive lists in one of the main markets (particularly new ingredients where full and up-to-date files are available) should at least be readily recognised and accepted by the competent authorities of the other major markets.

Greater transparency in the process for identifying ingredients of concern (i.e. how ingredients get on the agenda), investigating and decision-making would also be welcomed by industry and should assist in harmonisation of approaches to restrictions and prohibitions. Industry would welcome the regulation of substances in the EU being made as clear and logical as possible, so that the Annexes in the Cosmetics Directive can be more easily reproduced in third countries or regions.

Decision-making processes could also be made more effective, and potentially more harmonised, through mutually-agreed guidelines for industry and competent authorities on safety testing and data submission. This would reduce the delays experienced when competent authorities need to go back to industry for further information by ensuring that industry submissions were as complete as possible. This might also contribute to progress on the mutual acceptance of data.

Common Approaches to Safety Testing

Industry would welcome common approaches to safety testing, in particular regarding alternatives to animal testing. Non-alignment of approaches is seen as a significant potential barrier to future market development and product innovation.

Ideally, there should be mutual recognition of safety assessments, along the lines developed for pharmaceuticals. This is seen by industry as a long-term goal, however. In the short-term, the development of common international guidelines on safety testing could encourage progress towards this goal.

Common guidelines on stability testing would also provide the basis for harmonisation, and reduce costs for industry in meeting the different requirements currently operating in some regimes. Common guidelines on efficacy testing are considered to be more achievable than common efficacy standards. They would be particularly beneficial in areas such as sunscreens, where some regimes (e.g. the USA) have specified test methods that have been in place for some time and are considered out-dated, whilst elsewhere there are industry guidelines that are more flexible.

Common guidelines for cosmetics GMP could also be beneficial. Industry believes that the use of pharmaceuticals GMP for cosmetics is inappropriate. The existence of common guidelines for cosmetics GMP might provide an alternative, as well as ensuring a high standard of manufacturing practice in regimes where GMP requirements are not currently in operation.

Labelling and Packaging Rules

Greater alignment in labelling and packaging rules, so that packages do not need to be modified for different markets, would be welcomed by industry. There appears to be a growing consensus over the use of INCI terms for ingredient labelling, but more could be done to address the remaining requirements for translation of certain terms in certain markets (for example, translation of all terms in Brazil and translation of common terms in the USA and Canada).

The International Standards Organisation (ISO) is currently working on rules for the packaging, labelling and marking of cosmetics. This work is being undertaken by the TC217 which deals with cosmetics and is now at the

Enquiry Stage (Stage 4 of a 6-stage process) as a draft International Standard (DIS) which has been circulated to all ISO members for voting and comment within a period of five months. Stages 5 and 6 of the process are the approval and publication stages. These ISO rules on labelling, when published, could provide the basis for further harmonisation (ISO, 2004).

8.3.2 Actors

A range of organisations would have a role in implementing these measures, including the European Commission, national authorities (in the EU and elsewhere), international organisations and industry.

European Institutions

Actions that the European institutions could undertake to encourage harmonisation and innovation in the cosmetic industry comprise two aspects. The first is to take specific account of the international impact that new EU legislation will have, at the stage when proposals are being made, to ensure that changes do not present a barrier to harmonisation. In particular, when the Commission proposes timelines for implementation of new requirements (e.g. new labelling requirements, new regulations on substances, animal testing and marketing bans), it should take into account the implications for exports from and imports into the EU

The second aspect is an increased role for the EU at international level, including for example:

- to continue providing funds for capacity-building measures on technical issues where third countries might need assistance. Examples where this has already been successful include assistance provided under the EU-ASEAN co-operation programmes on in-market control, product safety and GMP and assistance to Russia under the TACIS programme. There may be scope to extend such assistance to other emerging markets, such as Mercosur;

- exploring the feasibility of working towards mutual recognition of substances included in positive lists of other major markets. Initially, this could involve exchange of information and analysis, leading towards mutual recognition of evaluation and assessment criteria, for both positive and negative lists; and

- further dialogue on regulatory issues with competent authorities in emerging markets. For example, the dialogue between the Chinese GAQSIQ and DG Enterprise could be extended to other countries.

Regulatory Authorities

Regulatory authorities have a key role to play in implementing the measures to enhance alignment and innovation set out in Section 8.3.1. Valuable progress has been made in the past on alignment of regulatory frameworks through the Cosmetics Harmonisation International Co-operation (CHIC) meetings between regulators in the major markets, in which the European Commission also participates. Such meetings have not been held since 2000 but it is understood that plans are under way to revive the process.

Bilateral agreements between the EU and regulatory authorities in other countries, for example on GMP guidelines and inspection, can also assist industry to achieve compliance in a cost-effective manner.

Regulatory authorities also have a key role to play in the harmonisation of cosmetics regulations at a regional level, by effective implementation of measures such as the Mercosur and ASEAN initiatives. Within the EU, there may be scope for further alignment between Member States of approaches to the regulation of borderline products, including controls over their distribution, and co-operation in in-market surveillance.

International Organisations

A number of international organisations can play a role in enhancing alignment of regulatory frameworks for cosmetics. These include:

- OECD: mutual acceptance of testing methods, particularly validation of alternative testing methods. The timetable for adoption of alternative test methods in the 7th Amendment is challenging; to ensure that market disruptions are minimised, OECD validation processes will need to be closely co-ordinated with those within the EU; and

- ISO: development of international standards and guidelines on cosmetics. ISO Technical Committee 217, responsible for standardisation in the field of cosmetics, is currently preparing standards on GMP, labelling requirements, microbiology and nitrosamine whilst Technical Committee 106 (on standardisation in dentistry) is working on a standard for toothpaste and mouth rinses.

Industry

Industry is already involved in a number of initiatives to enhance mutual understanding of regulatory frameworks and their implications. These include the three-yearly Mutual Understanding Conferences, bringing together industry representatives and regulators from around the world as well as ongoing dialogue between industry associations in the major markets.

Industry also has a key role to play in encouraging regulatory alignment through the development of international guidelines. Some such guidelines have already been agreed, for example the SPF testing methodology developed by Colipa, JCIA and CTFA-South Africa and the IFRA codex of fragrances.

There is considerable scope for additional work in this area, for example on mutually-agreed testing guidelines for safety, stability and efficacy. If industry is able to present an internationally-agreed position on these issues to regulators, this could provide an efficient and effective way to promote further alignment of regulatory practices without necessarily requiring major legislative changes.

PART V

BIBLIOGRAPHY

9. BIBLIOGRAPHY

ANMAT (1998): **Resolution Number 155/98 of the Ministry of Health and Social Action on Cosmetics, Personal Hygiene Products and Perfumes**, **July 13 1998**, Buenos Aires, Argentina, National Administration of Pharmaceuticals, Foods and Medical Technology.

ANVISA (2000): **Resolution RDC No. 79, of August 28, 2000 on Cosmetics, Personal Hygiene Products and Perfumes**, Brasília, Brazil, National Health Administration Agency.

CoE (2001): **Cosmetic Products - Borderline Situations**, Strasbourg, France, Council of Europe.

Colipa (2004): **The European Cosmetic, Toiletry and Perfumery Market 2003**, Brussels, Belgium, Colipa.

Colipa (2004b): **Colipa's Response to Consultation for Comparative Study on Cosmetic Legislation**, Brussels, Belgium, Colipa.

Colipa (2003): **International SPF: prepared by Colipa, CTFA-SA and JCIA**, Brussels, Belgium, Colipa.

Colipa (2001): **The European Cosmetic, Toiletry and Perfumery Market 2001**, Brussels, Belgium, Colipa.

CTFA (2001): **CTFA International Regulatory Resource Manual**, 5th Edition, Washington, DC, USA, Cosmetic, Toiletry and Fragrance Association.

EC (1998): **Directive 98/8/EC of the European Parliament and of Council on the placing on the market of Biocidal Products**, Brussels, Belgium, European Commission.

EC (1999): **Cosmetics Legislation, The Rules Governing Cosmetic Products in the European Union, European Commission, Volume 1**, Brussels, Belgium, European Commission.

EC (2004): **Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use (or Medicinal Products Directive),** Brussels, Belgium, European Commission.

EC (2003): **Directive 2003/15/EC of the European Parliament and of Council of 27 February 2003 amending Council Directive 76/768/EEC on the Approximation of the Laws of the Member States relating to Cosmetics Products**, Brussels, Belgium, European Commission.

EC (2003b): **Proposal for a Regulation of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorisation and Restriction of CHemicals (REACH)**, (COM(2003)64.4), Brussels, Belgium, European Commission

Eurostat (2003): **Eurostat Databases**, Luxembourg, Statistical Office of the European Communities.

Health Canada (2004): **An Act Respecting Food, Drugs, Cosmetics and Therapeutic Devices (Food and Drugs Act)**, Ottawa, Canada, Health Canada.

Health Canada (2003a): *List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient Hotlist)*, October 2003, downloaded from the Cosmetics Programme, Product Safety Programme, Health Canada website: www.hc-sc.gc.ca/hecs-sesc/cosmetics/hotlist_intro.htm

Health Canada (2003b): *Natural Health Products Regulations*, downloaded from the Natural Health Products Directorate, Health Canada website: www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/nhp_regs_e_html

Heerink B (2003): *The Economic Outlook for the European Cosmetic Industry in a Changing Regulatory Environment,* Paper presented at the Mutual Understanding Conference, 21 October 2003, Tokyo, Japan.

ISO (2004): *Cosmetics - TC 217*, Information downloaded from the International Standards Organisation website: www.iso.ch/iso/en/stdsdevelopment.html

MHLW (2001): **Japanese Pharmaceuticals Affairs Law**, Tokyo, Japan, Ministry of Health, Labour and Welfare.

PMoH (2000): **Health Code, Article 280, Law No. 1119/97, Decree 17057, GMC/Res/24/95**, Asunción, Paraguay, Ministry of Health.

RPA (2003): **Business Impact Assessment of the 7th Amendment to the Cosmetics Directive**. **Final Report**, Brussels, Belgium, Colipa.

SFDA (1999): **Hygiene Standard for Cosmetics**, Beijing, China, State Food and Drug Administration.

SFDA (1994): **Particulars of Implementation of Production Licence of Cosmetics**, Beijing, China, State Food and Drug Administration.

SFDA (1991): **Particulars of Implementation of Hygienic Inspection Regulations for Cosmetics**, Beijing, China, State Food and Drug Administration.

SFDA (1990): **Regulations for the Hygiene Supervision of Cosmetics**, Beijing, China, State Food and Drug Administration.

TGA (1998): **Standard AS/NZS 2604:1998 of 8 October 1998**, Canberra, Australia, Therapeutic Goods Administration.

UMoH (1995): **Uruguayan Law No.15.443, 15.703, Decree 252/987 and Decree 95/90**, Montevideo, Uruguay, Chemical and Pharmaceutical Division, Ministry of Public Health.

USCS (2003): **Cosmetic Trade Data**, Hong Kong, China, US Commercial Service, Hong Kong Business Update.

US FDA (2003): *Inspection of Cosmetics*, Office of Cosmetics and Colors, CFSAN, FDA. February 25, 2003. Article downloaded from the Centre for Food Safety and Applied Nutrition, US Food and Drug Administration website: www.cfsan.fda.gov/~dms/cos-214.html

US FDA (2002): *Is it a Cosmetic, a Drug, or Both? (or is it a Soap?)*, Office of Cosmetics and Colors, CFSAN, FDA. July 8, 2002. Article downloaded from the Centre for Food Safety and Applied Nutrition, US Food and Drug Administration website: www.cfsan.fda.gov/~dms/cos-218.html

US FDA (2000): *Prohibited Ingredients and Related Safety Issues*, Office of Cosmetics and Colors Fact Sheet, CFSAN, FDA. March 30, 2000. Article downloaded from the Centre for Food Safety and Applied Nutrition, US Food and Drug Administration website: www.cfsan.fda.gov/~dms/cos-210.html

US FDA (1999): *Sunscreen OTC Products Monograph, Federal Register 21.5.99*, Washington DC, USA, Federal Drugs Administration

US FDA (1992): *Cosmetic Handbook Part 1: Regulatory Requirements for Marketing Cosmetics in the United States*, FDA/Industry Activities Staff Booklet: 1992, Article downloaded from the Centre for Food Safety and Applied Nutrition, US Food and Drug Administration website: www.cfsan.fda.gov/~dms/cos-hdb1.html

US FDA (1960): **Food, Drugs and Cosmetics Act of 1938 and the Colour Additives Amendment of 1960**, Washington DC, USA, Federal Drugs Administration.

10. LIST OF CONSULTEES

Competent Authorities

EU	DG Enterprise, European Commission
US	United States Food and Drug Administration
Japan	Japanese Ministry of Health, Labour and Welfare
Canada	Health Canada
Argentina	National Administration of Pharmaceuticals, Food and Medical Technology (Argentina)
Brazil	Brazilian Sanitary Surveillance Agency (ANVISA)

Trade Associations*

EU	European Cosmetic, Toiletry and Perfumery Association
	European Federation for Cosmetic Ingredients (EFfCI)
	European Fragrance and Flavour Association
US	Cosmetics, Toiletries and Fragrances Association (CTFA)
Japan	Japanese Cosmetics Industry Association
Canada	Canadian Cosmetics, Toiletries and Fragrances Association
Argentina	Asociación Argentina de Qúimicos Cosméticos (AAQC)
	Camara Argentina de la Industria de Cosmetica y Perfumeria (CAPA)
Brazil	Brazilian Association of Personal Hygiene, Perfume and Cosmetics (ABIPHEC)

Consumer Organisations

EU	BEUC (The European Consumers' Organisation)

*A number of individual companies also provided detailed information used in this Report.

ANNEX 1

TECHNICAL SPECIFICATIONS

ANNEX I: TECHNICAL SPECIFICATIONS

CONTEXT OF THE STUDY

DG ENTR commissions this comprehensive study to explore the different approaches taken in different markets so as to identify similarities and divergences in cosmetics legislation at the international level.

Regulatory frameworks are considered determinants in defining the competitiveness and the economic viability of an industry and can lead to negative repercussions in international trade. Given this commonly held notion, a detailed analysis of the different regulatory frameworks for cosmetic products in the EC and major non-European markets, in particular in regard to the U.S., Japan and Canada, and an in-depth-analysis of the externalities associated with the different legislative approaches is deemed necessary.

Other major markets in emerging economies should be given adequate consideration. In addition, the study should take stock of the impact of different approaches on other nations/trade areas and their propensity to emulate regulatory approaches advocated in the three above-mentioned major markets. To analyse the economic impact, a concise analysis of major markets for cosmetic products should be provided, in particular in terms of market size and local production specified by major product groups.

In the context of the study specific attention should be given to so-called borderline products. For the purpose of this study borderline products are defined as products which may be considered cosmetic products or fall under other categories (e.g. pharmaceutical product, biocides or pertaining to any other category). These discrepancies and their political/economic implications require a detailed analysis.

OBJECTIVE OF THE STUDY

The envisaged study on the impact of cosmetics and related legislation should analyse the content, principles and motivation of stances different administrations advocate while regulating cosmetic products as well as the effects and implications these approaches have on the industrial competitiveness, safety, international acceptance of often diverging policies and subsequently the propensity of administrations to emulate the regulatory models of lead markets.

The study should identify opportunities and risks for future developments in the European model of cosmetics legislation and identify the mainstream developments and/or tendencies of cosmetics legislation at the international level. In particular the study should look at possible shortcomings of the current regulatory approaches in view of the recent or foreseeable technological, societal and environmental developments.

The impact analysis of the cosmetics policies should be accompanied by a sound collection of evidence and concrete recommendations for decision-makers. These recommendations should be particularly targeted at European and national policy makers and other European stakeholders.

DESCRIPTION OF WORK

The study should produce a qualitative and quantitative compilation, analysis and impact assessment of cosmetics legislation in the European Union vis-à-vis other major markets, i.e. the U.S., Japan, Canada and two other exemplary emerging markets still to be defined.

It shall identify and analyse the different models of legislation, its content, and its motivation. Based on these findings, it shall assess the impact of the regulatory framework on the cosmetic industry, its international competitiveness and future trends in legislation. Particular attention should be given to so-called borderline products, which are regulated – depending on the respective regulatory framework - under different sector-specific legislation (e.g. cosmetics, pharmaceuticals, foodstuff or biocides).

In particular, the following aspects have to be taken into account:

- identifying the principles and major policy objectives pursued by the different regulatory approaches for cosmetic products
- identifying major markets where these principles/models are applied
- identifying the advantages and disadvantages of the different policy instruments and mechanisms implementing the policy objectives in the different countries
- providing a comprehensive overview of the consequences of the different regulatory frameworks and actual measures companies have taken to comply with the various regulatory regimes

In addition the study shall address the following issues:

- a concise analysis of major markets in terms of production specified by major product groups
- examples elucidating the relevance of legislation in obtaining market access, achieving economies of scale and in performing on global markets
- the role trade aspects, innovation as well as concerns in regard to public health, safety of workers, consumer and environmental protection play in determining the respective regulatory approach
- the impact of recent or foreseeable technological developments in the regulatory approach
- the role of public authorities and manufacturers in ensuring the protection of the health of consumers
- the economic impact of different legislative approaches on trade flows, business practices, contracting, product quality and knowledge transfer and its influence on national legislation.
- with regard to the international aspects, issues such as the impact of different legislative framework on other markets, in particular the influence of the EU, the U.S. and the Japanese approaches and the propensity to emulate the approaches in perceived lead markets by other regulators
- the prospects and advantages of a harmonised approach by the major international partners in designing a regulatory framework that enhances the already present global nature of the industry.

WORK PLAN

In the tender, bidders shall produce a detailed work plan, which defines milestones for major deliverables. Bidders shall specify the methods for qualifying and/or measuring the impact of the regulatory framework, and also for obtaining/collecting the relevant information and/or data. Bidders are asked to propose ideas for the presentation of the results, which would enable stakeholders to take action.

The tender should be presented in the same order as indicated in Annex 5.3.

OBLIGATIONS OF THE CONTRACTOR

The Contractor agrees to :

- prepare the documents as requested in article 4.2. of these specifications.
- discuss the preliminary outline with the European Commission
- discuss the interim report with the European Commission (and take into account the Commission's comments).
- stay in close contact with the responsible services of the Commission (DG Enterprise F.3) and shall be required to contact the relevant contact person or his/her deputy every two weeks by telephone, fax or e-mail.

REPORTS AND DOCUMENTS

The Contractor is to provide the required reports and documents in accordance with the conditions of the standard service contract appended in Annex 5.4.

The Contractor shall :

- prepare a preliminary outline defining the approach, stating the methodology and identifying two emerging markets to be analysed no later than 8 weeks after signing the contract.
- prepare an interim report stating the main ideas and preliminary findings, no later than 4 months after signing the contract. Taking into account these findings and the objectives of the study, the Commission will determine the exact focus of the study after consulting with the contractor.
- prepare a draft final report containing the results of the study. This report shall be submitted to the Commission no later than 7 months after signing the contract.
- prepare a final report summarising the findings and making pragmatic recommendations for business and policymakers submit the report to the Commission no later than 8 months after signing the contract. The final report shall consist of five parts:

  Part I : Executive Summary
  Part II : Principles and Details of Different Regulatory Frameworks for Cosmetic Products including so-called Borderline Products
  Part III : Propensity of Third Countries to model their respective Legislation after Perceived Lead Legislation
  Part IV : New Developments/Trends in Cosmetics Legislation
  Part V : Bibliography

ANNEX 2

COMPARATIVE LIST OF UV FILTERS WHICH SUNSCREEN PRODUCTS MAY CONTAIN IN THE EU, US, JAPAN, CANADA, KOREA AND AUSTRALIA

Table A2.1: Comparative List of UV Filters which Sunscreens may Contain in the EU, US, Japan, Canada, Korea and Australia							
INCI Names	**Reference No In Annex VII/I of the CD 76/768/EEC**	**Europe (Maximum Authorised Concentration)**	**United States (Maximum Authorised Concentration)**	**Japan (Maximum Authorised Concentration)**	**Canada (Maximum Authorised Concentration)**	**Korea (Maximum Authorised Concentration)**	**Australia (Maximum Authorised Concentration)**
PABA	1	4-Aminobenzoic acid 5%	Aminobenzoic acid (PABA) 15%	Aminobenzoic acid (PABA) and its esters 4% (as total)	PABA 15%	PABA 0.5-5%	Aminobenzoic acid 15%
Camphor benzalkonium methosulfate	2	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidene-methyl) anilinium methyl sulphate 6%					
Homosalate	3	Homosalate (INN) 10%	Homosalate 15%	Homomenthyl salicylate 10%	Homosalate 15%	Homosalate 0.5-10%	Homosalate 15%
Benzophenone 3	4	Oxybenzone (INN) 10%	Oxybenzone 6%	2-Hydroxy-4-methoxybenzophenone (1) no limit (2) (3) 5%	Oxybenzone 6%		Oxybenzone 10%
Phenylbenz-imidazole sulphonic acid	6	2-Phenylbenz imidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts 8%(expressed as acid)	Phenylbenzimidazole sulphonic acid 4%	Phenylbenzimidazole sulphonic acid (1) (2) 3%	Ensulizole 8%	Phenylbenzimidazole sulphonic acid 0.5-4%	Phenylbenzimidazole sulphonic acid 4%
Terephthalylidene dicamphor sulfonic acid	7	3,3'-(1,4Phenylene-dimethylene) bis (7,7-dimethyl-2-oxo-bicyclo-[2.2.1] hept-1-ylmethane sulphonic acid) and its salts 10% (expressed as acid)		Terephthalylidene dicamphor sulfonic acid (1) (2) 10%	Terephthalylidene dicamphor sulfonic acid 10%	Terephthalylidene dicamphor sulfonic acid Not determined	Ecamsule 10%

Table A2.1: Comparative List of UV Filters which Sunscreens may Contain in the EU, US, Japan, Canada, Korea and Australia							
INCI Names	**Reference No In Annex VII/I of the CD 76/768/EEC**	**Europe (Maximum Authorised Concentration)**	**United States (Maximum Authorised Concentration)**	**Japan (Maximum Authorised Concentration)**	**Canada (Maximum Authorised Concentration)**	**Korea (Maximum Authorised Concentration)**	**Australia (Maximum Authorised Concentration)**
Butyl methoxydibenzoyl methane	8	1-(4-Tert-butylphenyl)-3-(4-methoxyphenyl) propane-1,3-dione 5%	Avobenzone 3%	4-tert-Butyl -4'-methoxydibenzoyl methane 10%	Avobenzone 5%	Butyl methoxydibenzoyl methane 0.5-5%	Butyl methoxy dibenzoylmethane 5%
Benzylidene camphor sulfonic acid and salts	9	alpha-(2-Oxoborn-3-ylidene) toluene-4 sulphonic acid and its salts 6% (expressed as acid)					alpha-(2-Oxoborn-3-ylidene) toluene-4 sulphonic acid and its salts 6% (expressed as acid)
Octocrylene	10	2-cyano-3,3-diphenyl acrylic acid, 2-ethyl-hexyl ester (Octocrylene) 10% (expressed as acid)	Octocrylene 10%	Octocrylene 10%	Octocrylene 12%	Octocrylene 0.5-10%	Octocrylene 10%
Polyacrilamido-methyl benzylidene camphor	11	Polymer of N-(2 and 4)-[(2-oxoborn-3-ylidene) methyl] benzyl}acrylamide 6%					
Octyl methoxy-cinnamate	12	Octyl methoxy-cinnamate 10%	Octyl methoxy-cinnamate 7.5%	2-Ethylhexyl-4-methoxy-cinnamate (1) (2) 20% (3) 8%	Octinoxate 8.5%	Octyl methoxy-cinnamate 0.5-7.5%	Octyl methoxy-cinnamate 10%
PEG-25-PABA	13	Ethoxylated ethyl-4-amino-benzoate (PEG-25 PABA) 10%					Ethoxylated ethyl-4-amino-benzoate (PEG-25 PABA) 10%
Isoamyl p methoxy-cinnamate	14	Isopentyl-4-methoxy-cinnamate (Isoamyl p-methoxycinnamate) 10%					Isoamyl methoxycinnamate 10%

Table A2.1: Comparative List of UV Filters which Sunscreens may Contain in the EU, US, Japan, Canada, Korea and Australia							
INCI Names	**Reference No In Annex VII/I of the CD 76/768/EEC**	**Europe (Maximum Authorised Concentration)**	**United States (Maximum Authorised Concentration)**	**Japan (Maximum Authorised Concentration)**	**Canada (Maximum Authorised Concentration)**	**Korea (Maximum Authorised Concentration)**	**Australia (Maximum Authorised Concentration)**
Octyltriazone	15	2,4,6-Trianilino-(p-carbo-2'-ethylhexyl-1'-oxy)-1,3,5 triazine (Octyl triazone) 5%		2,4,6,-tris(4-(2-ethylhexyloxy-carbonyl) aniline)-1,3,5-triazine (1) (2) 5%		Octyltriazone 0.5-5%	Octyltriazone 5%
Drometrizole trisiloxane	16	Phenol,2-(2H-benzo-triazol-2-yl)-4 methyl-6-(2-methyl-3-(1,3,3,3 tetramethyl-1-(trimethyl-silyl) oxy)-disiloxanyl) propyl) (Drometrizole Trisiloxane) 15%		Drometrizole Trisiloxane (1) (2) 15%			Drometrizole Trisiloxane 15%
Dioctyl butamido triazone	17	Benzoic acid, 4,4-((6-(((1,1-dimethylethyl) amino) carbonyl) phenyl) amino)-1,3,5-triazine-2,4-diyl) diimino) bis-,bis(2-ethylhexyl) ester) 10%					
4-methylbenzylidene camphor	18	3-(4'-Methylbenzyl-idene) -d-1 camphor (4 methylbenzylidene camphor) 4%			Enzacamene 6%		4 methylbenzylidene camphor 4%
3-Benzylidene camphor	19	3-Benzylidene camphor (3-Benzylidenecamphor) 2%					
Octyl Salicylate	20	2-Ethylhexyl salicylate (Octyl-salicylate) 5%	Octyl Salicylate 5%	Octyl Salicylate (2) 10% (3) 5%	Octisalate 6%	Octyl Salicylate 0.5-5%	Octyl Salicylate 5%

Table A2.1: Comparative List of UV Filters which Sunscreens may Contain in the EU, US, Japan, Canada, Korea and Australia							
INCI Names	**Reference No In Annex VII/I of the CD 76/768/EEC**	**Europe (Maximum Authorised Concentration)**	**United States (Maximum Authorised Concentration)**	**Japan (Maximum Authorised Concentration)**	**Canada (Maximum Authorised Concentration)**	**Korea (Maximum Authorised Concentration)**	**Australia (Maximum Authorised Concentration)**
Octyl dimethyl PABA	21	4-Dimethyl-amino-benzoate of ethyl-2-hexyl (octyl dimethyl PABA) 8%	Padimate O 8%	2-Ethylhexyl p-dimethylamino benzoate (1) (2) 10% (3) 7%	Padimate O 8%	Octyl dimethyl PABA 0.5-8%	Padimate O 8%
Benzophenone 4 Benzophenone 5	22	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid (Benzophenone-4) and its sodium salt (Benzophenone-5) 5% (of acid)	Sulisobenzone 10%	2-hydroxy-4-methoxybenzone-5-sulfonic acid an dits trihydrate (1) (2) 10% (3) 0.1% Sodium hydroxymethoxybenzophenone sulfonate (1) (2) 10% (3) 1%	Sulisobenzone 10%		Benzophenone 4 (Sulisobenzone) 10% Benzophenone 5 (Sulisobenzone sodium) 10%
Methylene bis-benzotriazolyl tetramethyl butylphenol	23	2,2'-Methylene-bis-6-(2H-benzotriazol-2yl)-4-(tetramethyl-butyl)-1,1,3,3-phenol 10%					Methylene bis-benzotriazolyl tetramethyl butylphenol 10%
Bisymidazylate	24	Monosodium salt of 2-2'-bis-(1,4-phenylene)1H-benzimidazole-4,6-disulphonic acid) 10% (of acid)					

Table A2.1: Comparative List of UV Filters which Sunscreens may Contain in the EU, US, Japan, Canada, Korea and Australia							
INCI Names	**Reference No In Annex VII/I of the CD 76/768/EEC**	**Europe (Maximum Authorised Concentration)**	**United States (Maximum Authorised Concentration)**	**Japan (Maximum Authorised Concentration)**	**Canada (Maximum Authorised Concentration)**	**Korea (Maximum Authorised Concentration)**	**Australia (Maximum Authorised Concentration)**
Anisotriazine	25	(1,3,5)-Triazine-2,4-bis((4-(2-ethyl-hexyloxyl)-2-hydroxy)-phenyl)-6-(4-methoxyphenyl) 10%					
Polysilicone-15	26	Dimethicodiethylbenzal malonate (CAS No 207574-74-1) 10%					
Titanium dioxide	27	Titanium dioxide 25%	Titanium dioxide 25%	Not regulated Considered as UV scattering agent No limit	Titanium dioxide 25%	Titanium dioxide 25%	Titanium dioxide 25%
				Mix isopropyle methoxy-C, and esters of diisopropylcinnamate (1) (2) 10%			
				1-(3,4-Dimethoxyphenyl 4,4-dimethyl-1,3-pentanedione (1) (2) 7%			
				2-Ethylhexyl dimethoxybenzylidene dioxoimidazolidine propionate (1) (2) 3%			
				4-(2-glucopyrano-siloxy) propoxy-2-hydroxybenzophenone (1) (2) 5%			

Table A2.1: Comparative List of UV Filters which Sunscreens may Contain in the EU, US, Japan, Canada, Korea and Australia							
INCI Names	**Reference No In Annex VII/I of the CD 76/768/EEC**	**Europe (Maximum Authorised Concentration)**	**United States (Maximum Authorised Concentration)**	**Japan (Maximum Authorised Concentration)**	**Canada (Maximum Authorised Concentration)**	**Korea (Maximum Authorised Concentration)**	**Australia (Maximum Authorised Concentration)**
Benzophenone 1				2,4-Dihydroxybenzophenone (1) (2) 10%			Benzophenone Permitted concentration to be determined
Benzophenone 2				2,2,4,4,-Tetrahydroxy-benzophenone (1) (2) 10% (3) 0.05%			Benzophenone 2 Permitted concentration to be determined
Benzophenone 6				Dihydroxy methoxy benzophenone (1) (2) 10%			
Benzophenone 8			Dioxybenzone 3%		Dioxybenzone 3%		Dioxybenzone 3%
Benzophenone 9				Disodium-2,2'-dihydroxy-4,4'-dimethoxy-5,5'-disulfo benzophenone (1) (2) 10%			
Cinoxate			Cinoxate 3%	Cinoxate (1) no limit (2) 5% (3) 5%	Cinoxate 3%	Cinoxate 0.5 – 5%	Cinoxate 6%
Methoxycinnamate salts (DEA, Na, K)					Diethanolamine methoxycinnamate 10%	Diethanolamine methoxycinnamate 0.5-8%	
Digalloyl trioleate						Digalloyl trioleate 0.5-5%	

Table A2.1: Comparative List of UV Filters which Sunscreens may Contain in the EU, US, Japan, Canada, Korea and Australia							
INCI Names	**Reference No In Annex VII/I of the CD 76/768/EEC**	**Europe (Maximum Authorised Concentration)**	**United States (Maximum Authorised Concentration)**	**Japan (Maximum Authorised Concentration)**	**Canada (Maximum Authorised Concentration)**	**Korea (Maximum Authorised Concentration)**	**Australia (Maximum Authorised Concentration)**
Diisopropyl methyl cinnamate				2,5-Diisopropyl methyl cinnamate (1) (2) 10%			
Glyceryl ethylhexanoate dimethoxy-cinnamate				Glyceryl octanoate di p-methoxy cinnamate 10%			
Drometrizole						Drometrizole 0.5-7%	
Ethyl dihydroxy propyl PABA					Ethyl dihydroxy propyl PABA 5%	Ethyl dihydroxy propyl PABA 0.5-5%	
Ethyl PABA				Aminobenzoic acid (PABA) and its esters 4% (as total)			
Ferulic acid				Ferulic acid (1) (2) 10%			
Glyceryl PABA					Glyceryl PABA 3%	Glyceryl PABA 0.5-3%	
Isopropyl benzyl salicylate							Isopropyl benzyl salicylate Permitted concentration to be determined
Lawsone + dihydro-acetone						Lawsone + dihydro-acetone 0.25% + 3%	

Table A2.1: Comparative List of UV Filters which Sunscreens may Contain in the EU, US, Japan, Canada, Korea and Australia							
INCI Names	**Reference No In Annex VII/I of the CD 76/768/EEC**	**Europe (Maximum Authorised Concentration)**	**United States (Maximum Authorised Concentration)**	**Japan (Maximum Authorised Concentration)**	**Canada (Maximum Authorised Concentration)**	**Korea (Maximum Authorised Concentration)**	**Australia (Maximum Authorised Concentration)**
Methylbis(trimethylsiloxy)silyl isopentyl trimethoxy cinnamate				Methylbis(trimethylsiloxy)silyl isopentyl trimethoxy Cinnamate (1) (2) 7.5% (3) 2.5%			
Menthyl anthranilate			Menthyl anthranilate 5%		Meradimate 5%	Menthyl anthranilate 0.5-5%	Menthyl anthranilate 5%
Pentyl dimethyl PABA				Amyl p-dimethylamino benzoate (1) (2) 10%		Pentyl dimethyl PABA 0.5-5%	
Salicylate salts (TEA, Na, K)						Salicylate salts (TEA) 12%	Salicylic acid salts (TEA, Na, K) Permitted concentration to be determined
Trolamine salicylate			Trolamine salicylate 12%		Triethanolamine salicylate 12%		Triethanolamine salicylate 12%
Zinc Oxide			Zinc oxide 25%	Not regulated Considered as UV scattering agent No limit	Zinc Oxide 20%	Zinc Oxide 25%	Zinc Oxide No limit