COSMETIC SAFETY REGULATIONS: A COMPARATIVE STUDY OF EUROPE, THE USA AND MALAYSIA

A THESIS SUBMITTED TO THE UNIVERSITY OF MANCHESTER FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN THE FACULTY OF HUMANITIES

2012

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Word count: 97,211 words
Abstract

The need for product safety regulation is no longer a source of debate. It should be the primary aim in any consumer protection policy. This is due to the fact that there are a lot of consumer goods that are heterogeneous and more technologically advanced that are continually being introduced to consumers. Cosmetic products are currently one of the most popular consumer products. Their increase in sales is evident globally including in developing countries. They are no longer solely associated with women but are being used by all people, of all ages. With such popularity, cosmetics producers are eager to make a profit, which sometimes has resulted in the introduction of cosmetics which are not safe and cause adverse effects. This suggests that there might be a loophole in the adequacy of the safety laws or regulations. The possibility of these safety issues occurring anywhere is generally acknowledged, which makes it a global issue. Although such cases are not as frequent as for other consumer goods such as foods or pharmaceuticals, there is a need to investigate the cosmetics safety mechanisms in order to see if consumers are adequately protected and if the safety mechanisms for cosmetics are efficient. In realising this aim, the study takes three jurisdictions to compare, namely the EU, the USA and Malaysia. Through analysis, the ideal features of cosmetics regulations based on the larger picture of safety regulation generally are also considered. This study contrasts the EU and Malaysia, that have in place government regulation of cosmetics, with the USA that has a different regime for cosmetics, more dependent on self-regulation. Out of the three, Malaysia is the newest country that has introduced a new law on cosmetic products and this has been adopted from the EU model. Although discussions on cosmetic regulations have been undertaken in Malaysia, the legal safety issues to which they give rise have not been investigated systematically in comparison with the EU and the USA. Even in these jurisdictions cosmetics safety is not discussed as much as other consumer products. This thesis also investigates why Malaysia has adopted the EU policy and not some other policy such as the American one. Once the above issues have been considered, the impact of the new emerging technology of nano-cosmetics is analysed. The thesis found that, Malaysia, as with any newly introduced system, has experienced some setbacks and encountered teething problems due to a lack of resources, structure, technical facilities and qualified personnel. However, as a developing nation, it certainly has benefited from the adoption of the EU system. Although there is still much room for improvement, this borrowing has benefited consumers, in so far as safety is concerned, because of the common and standard safety assessments and the responsibility of safety now being placed on the manufacturers. Consumers can also enjoy more products due to the elimination of trade barriers through free movement and cooperation between member states.
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List of Abbreviations

ACA  Asean Cosmetics Association
ACS  Asean Cosmetics Scientific Body
ACC  Asean Cosmetics Committee
ACCSQ  Asean Consultative Committee on Standard and Quality
ACD  Asean Cosmetic Directive
ACE  Adverse Cosmetic Effects
ACR  Adverse Cosmetic Reactions
AFTA  Asean Free Trade Area
AHA  Alpha Hydroxyl Acids
AHCRS  Asean Harmonised Cosmetic Regulatory Scheme
ALERT  Asean Alert System
ASA  Advertising Standard Authority UK
ASEAN  Association of South East Asian Nations
BEUC  European Union Consumer’s Organization
CR  Cosmetic Regulation
CDCR  Control Drug and Cosmetic Regulations
CFTA  Cosmetic Fragrance Toiletry Association
CFR  Code Federal Regulation
CIR  Cosmetic Ingredient Review
CLM  Cosmetic Labeling Manual
COMEST  Commission on Ethics &Scientific Knowledge and Technology
COSING  COSmetic INGredient
CPA  Consumer Protection Act
CPNP  Cosmetic Product Notification Portal
CPSA  Consumer Product Safety Act
CPSC  Consumer Product Safety Commission
CTFA  Cosmetic Toiletry and Fragrance Association
CTWG  Cosmetic Technical Working Group
CPTA  Personal Care Product Council
CSCA  California Safe Cosmetic Act
DPS  Director Pharmaceutical Services
DG SANCO  Directorate General Health and Consumer Protection
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<td>Department Health Services</td>
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<td>DTI</td>
<td>Department Trade Industry</td>
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<td>EC</td>
<td>European Commission</td>
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<td>ECA</td>
<td>European Cosmetics Association (COLIPA)</td>
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<td>ECPC</td>
<td>European Commission Pharmaceutical Cosmetic</td>
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<td>EEC</td>
<td>European Economic Community</td>
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<td>EPA</td>
<td>Environmental Protection Agency</td>
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<td>EPS</td>
<td>European Product Safety</td>
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<td>EPT</td>
<td>Common Effective Preferential Tariff</td>
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<td>EU</td>
<td>European Union</td>
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<td>EUCI</td>
<td>European Union Cosmetic Industry</td>
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<td>EUCD</td>
<td>European Union Cosmetic Directive</td>
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<td>EWG</td>
<td>Environment Working Group</td>
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<td>FDA</td>
<td>Federal Drug Agency</td>
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<td>FDA-CFSAN</td>
<td>Federal Drug Agency's Center for Food Safety and Nutrition</td>
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<td>FD&amp;CA</td>
<td>Federal Food Drug and Cosmetic Act</td>
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<td>FPLA</td>
<td>Fair Packaging and Labeling Act</td>
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<td>GAO</td>
<td>Government Accountability Office</td>
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<td>GATT</td>
<td>General Agreement of Tariff and Trade</td>
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<td>GBCEA</td>
<td>Guidance for Business Consumer &amp; Enforcement Authorities</td>
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<td>GGCP</td>
<td>Guidelines for Control of Cosmetic Products</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<td>GPSR</td>
<td>General Product Safety Regulation</td>
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<td>GPSD</td>
<td>General Product Safety Directive</td>
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<td>GRAS</td>
<td>General Recognized as Safe</td>
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<td>IBRC</td>
<td>Industrial Biotechnology Research centre</td>
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<td>ICTA</td>
<td>International Center for Technology Assessment</td>
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<td>ICCR</td>
<td>International Cooperation on Cosmetic Regulation</td>
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<td>IDCA</td>
<td>Irish Detergent and Cosmetic Allied</td>
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<td>INCI</td>
<td>International Nomenclature of Cosmetic Ingredients</td>
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<td>IRPA</td>
<td>Intensification of Research Property Area</td>
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<td>MHW</td>
<td>Ministry Health &amp; Welfare</td>
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<td>MHLW</td>
<td>Ministry Health Labour &amp; welfare</td>
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<td>MROB</td>
<td>Malaysian Registration of Business</td>
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<td>Abbreviation</td>
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<td>MOSTI</td>
<td>Ministry of Science Technology &amp; Innovative</td>
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<td>NCCC</td>
<td>National Consumer Complaint Centre</td>
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<td>NNR</td>
<td>National Nanotechnology Initiative</td>
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<td>NLC</td>
<td>Nanostructured Lipid Carrier</td>
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<td>NPCB</td>
<td>National Pharmaceutical Control Bureau</td>
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<td>OTC</td>
<td>Over the Counter Drug</td>
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<td>PAO</td>
<td>Period after Opening</td>
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<td>PCPC</td>
<td>Personal Care Product Council</td>
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<td>PIF</td>
<td>Product Information File</td>
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<td>PPP</td>
<td>Poison Preventing Packaging</td>
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<td>QCCPS</td>
<td>Quality Control Cosmetic Product Specific Legislation</td>
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<td>RAPEX</td>
<td>System of Rapid Exchange</td>
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<td>ROS</td>
<td>Radical Oxygen Species</td>
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<td>RPA</td>
<td>Risk &amp; Policy Analysts</td>
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<td>SCC</td>
<td>Scientific Committee on Cosmetology</td>
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<td>SCCP</td>
<td>Scientific Committee on Consumer Product</td>
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<td>SCCNFP</td>
<td>Scientific Committee on Cosmetic Product and Non-Food Product</td>
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<tr>
<td>SEA</td>
<td>Single European Act</td>
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<td>SIRIM</td>
<td>Standard and Industrial Research Institute of Malaysia</td>
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<td>SLN</td>
<td>Solid Lipid Nanoparticles</td>
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<td>SPF</td>
<td>Sun Protection Factor</td>
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<td>SPS</td>
<td>Sanitary and Phytosanitary Measure</td>
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<tr>
<td>TBT</td>
<td>Technical Barriers to Trade</td>
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<tr>
<td>USDA</td>
<td>Department of Agriculture Bureau</td>
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<td>VCRP</td>
<td>Voluntary Cosmetics Registration Program</td>
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Chapter 1: Introductory chapter

1.1 Background of the Study

The existence of numerous consumer products on the market today that are ever more sophisticated and complex attests to the global advancements in science and technology. It also reflects a change in the perception of modern consumers and their growing demands. One particular area of growth has been in personal care products, the subject of this thesis. A global survey conducted by Synovate\(^1\) based on seven thousand people in nine markets\(^2\) revealed that two thirds of all people surveyed said beauty was mainly about non-physical attributes. However, as many as forty percent said they would change their looks if they could.\(^3\) In a more recent study conducted by Harvard and Massachusetts General Hospital Researcher Partners with P&G Beauty & Grooming, it was held that the ‘make-up’ application could specifically impact judgements of attractiveness.\(^4\)

Among personal care products that are booming in the modern world are cosmetics. It has been suggested\(^5\) that the pressure to be well-groomed has resulted in massive sales of such products all over the world, even during times of recession.\(^6\) The need for cosmetics has become self-evident. Today, the innovation of new products coupled with the massive demand for them offers a great opportunity for those who aim for profit from the mass production of such products. This is in line with the principle of freedom of choice\(^7\) that ensures that consumers have a wide range of products to choose from. The most crucial consideration, however, is that

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\(^{2}\)The nine markets surveyed are Brazil, Bulgaria, Canada, Korea, India, Singapore, Spain, South Africa and the United States.


\(^{4}\)The study was conducted by Harvard and Massachusetts General Hospital Researcher Partners with P&G Beauty & Grooming and the result of the study has been published in PLOS ONE, 3 Oct 2011


the products available to be consumed are safe and are not a danger to the health of consumers. Accidents can happen as a result of unsafe products.

Modern product safety law came about to minimise preventable home accidents. Product safety regulations are aimed at preventing dangerous products from reaching the market or the consumer, as well as informing the user how to use the products safely, as intended. Cosmetics firms should also be responsible for withdrawing or notifying users of products that are recognised as being unsafe. It is not sufficient for the producers merely to design, create and sell products that are intended to be safe. The way the product is used may also affect the safety of those who use it or are affected by it. As part of the product development, it is also very important to inform the consumers about the instructions for use and the warning associated with the products, as well as to pay attention to the product’s packaging. Also important is the product monitoring system after they are sold on the market.

With the rise in popularity of cosmetic products, there has been a similar rise in reports\(^8\) of hazardous substances in cosmetics. The effects of these have sometimes been lethal. In Cambodia for example, there was a death due to a Vietnamese-made skin whitening cream believed to contain dangerous chemicals.\(^9\) As far back as the 1930s there were health scares involving cosmetics such as Koremlu cream\(^10\) and Lash Lure,\(^11\) and sometimes there were tragic consequences. There is no guarantee that similar catastrophic cases will not happen again in the future.

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\(^8\)For example, The Ministry of Health Malaysia has cancelled a product notification of a whitening cream from Japan following a detection of a scheduled poison heavy metal known as mercury. It has been reported in the Drug Control Authority Newsletter, Volume 52, No 30, June 2011. In Norway, the Norwegian Institute of Public Health has published a report entitled National Register of Adverse Effects from Cosmetic Products 2008-2010 that provides an overview of cosmetics’ adverse effect notifications that the registry received during the first two years of operation. See Granum, Berit and Lovik, Martinus, National Register of Adverse Effects from Cosmetic Product 2008-2010, March 2011, Folkehelseinstitutet, Oslo.

\(^9\) It was reported in the Bangkok Post, 'Skin Cream Linked to Bride’s Death,' 9 March 2010 at http://www.bangkokpost.com/news/local/34119/skin-cream-linked-to-bride-death, (last visited 5 July 2011)

\(^10\) It was a depilatory cream that contained the substance called thallium which caused poisoning in 1930s in the USA. See W.S. Duncan and E.H. Crosby, ‘A Case of Thallium Acetate Poisoning Following the Prolonged Use of a Depilatory Cream,’ Journal of American Medical Association (JAMA), 96, no. 22, 30 May 1931. Also mentioned in Sigmund Greenbaum and Jay Shamburg, ‘Reports of Thallium Acetate Poisoning Following the Use of Koremlu,’ Journal of American Medical Association (JAMA) 96, no 22, 30 May 1931.

future. The issue then arises as to whether such incidents could be safeguarded by a regulatory mechanism, i.e. by ensuring only safe cosmetic products reach the market. Here, product safety regulations play a fundamental role. Product safety refers to the regulatory control by governmental authorities of the marketing of products by means of criminal and/or administrative law. It functions as a preventive measure, particularly when consumers are not able to anticipate risks, and when so many new products are being introduced that are only supported by the claims of the manufacturers concerning their safety and effectiveness.12

1.2 The need for product safety regulation13

It is often argued by consumer advocates that consumers have inadequate information concerning the characteristics and efficacy of a product offered and that sellers will generally have superior information regarding these matters.14 This covers potentially many issues, but can include safety and related matters such as reliability and durability.15 This is called information asymmetry and can sometimes mean that consumers have difficulties in making decisions that reflect their true preferences. In addition, an insight provided by behavioural economics indicates that consumers may not always respond to information provided as reasonably as the economic models sometimes suggest.16 It has been argued that, if consumers have the correct information17 concerning the characteristics and efficacy of a certain product offered on the market, regulatory intervention, through the regulation of product safety, might not be required. This is on the proviso that such transactions do not give rise to ‘spill over’ effects which adversely affect individuals who are third parties to the transaction. These effects are also known as externalities.18 However, the more frequent predicament in the use of many products sold on the market,

13Note that this section is merely to introduce the subject. Chapter 2 discusses this subject thoroughly.
15Furthermore, although the consumers can obtain information from ingredients labelled on the packaging provided by the producer/manufacturer, it is still possible that they might have problems in absorbing the disclosed information effectively. See further discussions in Chapter 2.
17Chapter 2 thoroughly discusses information regulation.
18Externalities are also known as ‘spill over effects’ as termed by Ogus, op.cit., 2004, pp. 4, 21, 33-38. It refers to a consequence of economic activity/cost that is experienced by unrelated third parties. This will be explained further in chapter 2.
including cosmetics, is that their safety and quality can only be ascertained through long-term consumption, as the effects of poor quality products may take a considerable time to emerge.\textsuperscript{19}

In these cases, consumers are usually unable to establish the level of safety of goods or the quality of goods of particular products before purchase. This is due to the fact that in many consumer products, their safety aspects are determined through experience. This is known as ‘experience goods’ whereas another category of products is ‘search goods.’\textsuperscript{20} The search goods products are the products whose safety and quality can be determined prior to purchase, whereas those of experience goods can only be established during consumption.\textsuperscript{21} They are technically complex, and consumers are not usually able to examine the products to assess their claimed efficiency simply by inspecting them. It was argued that the potential danger of many consumer products was sometimes underestimated and rarely appreciated by the public.\textsuperscript{22} Therefore, the control of potential risk is an important component as far as product safety is concerned. To control the risk, a product needs to undergo a risk assessment. This approach focuses on the scientific understanding and measurement of hazards and ultimately the risks associated with them. Every product may need a different risk assessment.

It is also of equal importance under the product safety regime, to place the responsibility of safety on the producer or manufacturer of products. This is a cardinal principle since they manufacture the products in the first place. All of the above are known as pre-market control approaches, in other words products are controlled \textit{prior} to them being placed on the market. However, the responsibility on the producer does not stop after the product is released onto the market, but continues beyond. They also have a duty to monitor the products when they are on the market. This is called post-marketing obligations.

This thesis is concerned with the theory surrounding product safety regulations and how it relates specifically to cosmetics. It will investigate the existing

\textsuperscript{19}Ogus, \textit{op.cit.}, 2004, p. 190.
legal mechanisms in the cosmetic safety framework to determine whether they are adequate and efficient in protecting the safety of consumers. Through analysis, this thesis compares three different jurisdictions, namely; the EU, the USA and Malaysia. In contrast to the EU and Malaysia that exercise government regulation of cosmetics, the USA has been chosen as it has a different regime for cosmetics, which is largely through self-regulation. Among the three, Malaysia is the newest country that has introduced a law on cosmetic products through harmonisation of the cosmetic regulations among the ASEAN countries, on the basis of a new Cosmetics Directive which had been adopted from the EU Cosmetics Directive. For the purpose of providing an easier understanding of the background of Malaysia’s cosmetics regulations, it is important that harmonisation is also discussed.

1.3 Significance of this study

There have been numerous academic studies on general product safety regulations, such as those exploring the nature and purpose of the regulations as well as comparisons with product liability. In terms of safety regulation more generally, there have also been analyses of certain consumer products and their product safety. Food and drugs, for example, have been among the most analysed products in terms of safety regulation. Discussions of these have also included comparisons between jurisdictions. More recently, products such as toys have also been analysed from the perspective of their safety regulations. Cosmetic products and

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23The justifications for comparing the three jurisdictions are explained in section 1.4 of this chapter.
25Among the list of journals specifically provides discussions pertaining to food safety are Food Policy, Journal of Food Safety, Food and Chemical Toxicology, Critical Reviews in Food Science and Nutrition, International Journal of Food Science and Technology, Comprehensive Reviews in Food Science and Food Safety, Journal of Food Protection and Food Control.
their safety, however, have not been discussed as frequently as the above mentioned products, especially with regards to comparative discussions. More importantly, for a developing country like Malaysia, such a subject has rarely been specifically raised in any academic discussion or in any other literature in that national context. This absence is because cosmetic safety regulations have not frequently been researched in the jurisdiction. Another reason why there has been little discussion regarding the safety of cosmetics is because they are not normally associated with health problems.

Undoubtedly cosmetics are now being used by many people to improve their appearance. In the UK for example, The Daily Mail newspaper reported that in a 2006 survey commissioned by New Woman magazine, British women spent £3,000 a year on beauty products and treatment, with 81% of women wearing make-up everyday to feel confident. Another survey reported that the British women even spent more on their appearance than on their health.

Also, cosmetic products now attract a much wider market. In the past they used to be associated almost exclusively with women but now they have become important for both genders and all age groups. Cosmetics are produced on a larger scale and their sales are now astounding. In 2006 for instance, approximately 11 billion personal care products were sold within the United States, causing annual cosmetic sales to reach $62 billion dollars, and in the EU, the cosmetic industry is

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28 For example C. Hodges discusses cosmetics safety in his book the *European Regulation of Consumer Product Safety*, 2005, Oxford University Press. However, cosmetics as a subject is discussed together with other products such as medicines, biocides, and tobacco from within the EU product safety regulation.

29 *Food and Drug Law Journal* is used to be known as *Food Drug Law and Cosmetic Journal* and is the only journal that is specifically published for publishing discussion on cosmetics regulation, among with drugs and Food. Other related journals pertaining to cosmetics are *Journal of Cosmetic Dermatology* and *International Journal of Cosmetic Science*, however, the last two journals mentioned are on the scientific studies on cosmetic products.

30 One of the seminars which gave some academic insights is The National Cosmetic Seminar 2009 entitled ‘ASEAN Cosmetic Directive: Fostering Industry Compliance,’ organised by the National Pharmaceutical Control Bureau (NPCB), Kuala Lumpur with the collaboration of the Cosmetics Toiletries and Fragrance Associations, 19 Oct 2009

31 G. Kay for example, has claimed that recent scholarship on cosmetics ‘has largely ignored the devastating effect of serious accident’ caused by cosmetic on consumers. See G. Kay, 2005, supra, p. 2.


34 Cosmetic products are also used among men. It was suggested that dynamism in men’s grooming products especially the skincare has been identified as one of the core prospect products sector. See Euromonitor, *Cosmetics and Toiletries -World*, 2007, Euromonitor International.

worth £67 billion.\textsuperscript{36} The large size of the market is clear, not just from the developed markets such as the EU and the USA. The trend can also be seen in developing countries such as Malaysia. It was reported that Malaysians spent an estimated $500 million in 2006 on cosmetics, which almost doubled within a year.\textsuperscript{37}

As the sales of cosmetics increase\textsuperscript{38} around the world, the problems concerning the safety of such products have also become a global problem. In Malaysia, there have been reports indicating that Malaysian women like to use whitening products. In 2006, A New York Times report has quoted a survey conducted by a market research company, Synovate, which found that four out of every ten Malaysian women used whitening products.\textsuperscript{39} The National Pharmaceutical Control Bureau of Malaysia (NPCB), a bureau which is responsible for controlling the cosmetics on the market, revealed that out of the whitening products used, many of them contained prohibited ingredients such as hydroquinone acid, tretinoin and mercury.\textsuperscript{40}

This study contends that there is a need to investigate the cosmetic safety regulations under the fundamental theoretical framework of general product safety regulations. The examples concerning the safety of cosmetic products discussed above suggest that there might be loophole in the adequacy of the safety laws or regulations. The probability of the said safety issues also happening in other jurisdictions is generally acknowledged, which makes it a global issue. As mentioned previously, although discussions on cosmetic regulations are undertaken, the legal safety issues to which they give rise have not been investigated systematically in Malaysia in comparison with the EU and the USA, and even in these jurisdictions cosmetics safety is not often discussed as much as other consumer products. In addition, since Malaysia is new in introducing regulation, which was implemented through the Guidelines for Control of Cosmetic Products 2009 adopted from the

\textsuperscript{36}This figure is according to the European Cosmetic Association (COLIPA) in the COLIPA Annual Report 2010.
\textsuperscript{37}Asia Pacific Cosmetic & Toiletries Market Overview, 2005, Volume 1, pp. 1-8.
\textsuperscript{38}For example, L’Oreal recorded a historically high net profit of €1,506 million in the first-half of fiscal of 2011. Additionally, the company achieved improvement in gross profit at 71.5%, sustained investments in R&D and advertising and promotion, and an operating margin of 16.8%. See the report in the Global Cosmetic Industry magazine at http://www.gcimagazine.com/business/marketers/financials/128827443.html (last accessed 11 October 2011).
\textsuperscript{40}Zuraida Abdullah ‘Post marketing Surveillance Activities: Findings and Recommendations,’ The National Cosmetic Seminar 2009 by National Pharmaceutical Control Bureau (NPCB), Kuala Lumpur.
ASEAN Cosmetic Directive, it is very timely to analyse the implementation of the new scheme and to examine the reasons why it has chosen such a policy for its cosmetic regulation.

This thesis starts by analysing the theory of product safety regulations. It is pertinent as the understanding of the theory of the general product safety regulations helps in understanding the case study of cosmetic safety regulations. Subsequent discussions focus on cosmetic regulations in the EU, followed by those of the USA, and, lastly, in the analysis of Malaysia’s scheme. A later chapter provides an analysis of differences between the three compared jurisdictions as far as the regulations of cosmetics safety are concerned. This will include the analysis of Malaysia’s scheme which has moved from cosmetic registration to cosmetic notification. Lastly, a case study concerning a newly emerging technology being used in cosmetic products; nanotechnology appears in the penultimate chapter. It is crucial to explore such a new technology in this discussion as questions concerning the safety of certain types of nanotechnology used in cosmetic products have been raised prominently in recent discussions.

1.4 Scope of Analysis: Comparative Analysis of the EU, the USA and Malaysia

As previously mentioned, the central task of this thesis is to examine product safety regulations by taking cosmetic products as the case study. This will be done by comparing three different jurisdictions; Malaysia, the EU and the USA. The inclusion of a comparative study is relevant due to the increasing influence of international legal materials, as well as the increasing need to refer to materials from a variety of jurisdictions, especially as cosmetics safety are now a globalised phenomenon. It should be noted that one of the most important developments in the subject of global cosmetic safety regulations is the harmonisation of various national laws, as is the case in the member countries of the European Union and more recently, by the member countries of ASEAN. It is noteworthy that the harmonisation in the respective member countries has seen the elimination of differences in national

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41 This is explained in the theoretical chapter (chapter 2) and in Malaysian chapter (chapter 5).
42 That is in the theoretical chapter (chapter 2).
43 A thorough discussion is provided in chapter 7.
45 By virtue of the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS) which was signed on 2 September 2003.
legislation concerning labelling, composition, and permitted ingredients in regions like the EU and ASEAN.\textsuperscript{46} In the past, variations in cosmetic regulations undoubtedly affected international trade and the creation of a global market. Such regulations also have an impact on the degree of safety provided to consumers within different countries.

The EU regulations were chosen as the model for the ASEAN Directive, as it was considered to be at the forefront in the regulation of the safety of cosmetics\textsuperscript{47} and in initiating many new policies on cosmetics. The development in the cosmetic regulations in the EU provides a reference for many countries, including the ASEAN countries. New policies were introduced in the EU Cosmetics Directive including an amendment to prohibit the testing of animals.\textsuperscript{48} The EU has also been at the forefront of research of the new emerging technology in the cosmetic sector that is nanotechnology.\textsuperscript{49}

Another jurisdiction compared in this thesis is the USA, which is known for its long history of regulating cosmetics. The USA is also acknowledged as being a centre for academic analysis in this area. For example, The Food Drug Cosmetic Law Journal, now known as Food Drug Law Journal, is a publication that was established in 1946 specifically for any relevant studies concerning cosmetic regulations. While the EU Cosmetic Directive was introduced in 1976,\textsuperscript{50} the USA’s Food and Drug Act of 1938 is the oldest law on cosmetics. What makes it a very significant jurisdiction, despite this law, is that the cosmetic policy in the USA is centred on self-regulation, which is different to the legislation-driven practices of most other countries.\textsuperscript{51} Due to this, it is particularly relevant to include the USA as a jurisdiction in this thesis.

\textsuperscript{47}The EU cosmetic industry was estimated to be worth of € 58.1 billion and it represents one third of the global market – that is more than the combined USA and Japanese market, COLIPA Annual Report of 2010.
\textsuperscript{48}The EU Court of Justice and Advocate General held against France and upheld the 17\textsuperscript{th} amendment of the EU Cosmetic Directive. Case C-244/03, 2003, O.J (C 171).
\textsuperscript{49}See further discussion in chapter 7.
\textsuperscript{50}Prior to the introduction of the EU Cosmetic Directive in 1976, cosmetics were regulated under each member countries’ national laws.
\textsuperscript{51}Some academic writers have suggested that cosmetics in the USA are among the least regulated products on the market and that the USA’s Federal Drug Administration (the FDA) requires more stringent standards. (Further details in chapter 4).
As for the inclusion of Malaysia’s jurisdiction for comparison, it is important to explore the cosmetic regulation scheme of a developing country. In Malaysia, following the harmonisation with the other ASEAN countries on cosmetic regulations, the new procedure has completely replaced the old system. The ASEAN Cosmetics Directive (ACD), which was introduced on 1 January 2008, was adapted from the EU Cosmetics Directive. It is, therefore, relevant to analyse the implementation of the new Directive and to examine why EU law was considered to be the best system to be applied for its policies on cosmetics. Furthermore, it will be possible to see how the adaptation of cosmetic regulations provides a better standard for cosmetic safety in this country as Watson states ‘borrowing from another legal system is the most common form of legal change.’ It has also been stated that ‘[i]n countries that have adopted codes or institutions which originated from another system, it has been natural to look at the way that the system has developed and has been developed in its original habitat.’ This is especially so as Malaysia emerged from colonial rule with laws identical in most aspects to that of its colonising country, that is, the UK.

1.5 A brief introduction to the regulation concerning cosmetics in the EU, the USA and Malaysia

In the EU, during the early years, national regulation of cosmetic products was part of the larger problem of non-tariff barriers to free trade among the member states. These differences in national regulatory schemes obligated producers of cosmetic products to adapt their production practices to the different countries’ varying provisions. Consequently, in 1976, the EEC issued a Directive establishing a single set of rules for cosmetics. The EU does not have any requirement for cosmetic products

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52 Since both the USA and the EU are developed regions, taking a developing country is another way of comparison.
53 The registration system has been replaced with a notification system, in which the company responsible for placing a cosmetic product on the local market must submit notification to the relevant cosmetic authority prior to market, manufacture, import or sale by wholesale of their cosmetic products.
54 EU Cosmetic Directive 76/768/EEC.
57 Malaysia has earlier been colonised by the Portuguese in 1511, but later on was taken over by the Netherlands in 1641. The British took over Malaysia from the Netherlands in 1824 by virtue of the Anglo-Dutch Treaty. Although being colonised by 3 different colonies, the law for the country’s administration mostly came from the British.
to be registered. The regulation of cosmetics is determined based on ensuring the safety of their ingredients. Also, the general obligation for cosmetics safety specified in the EU is that ‘a cosmetic must not be liable to cause damage to human health when applied under normal or reasonable foreseeable conditions of use.’ On 30 November 2009, the new Cosmetic Regulation was adopted, replacing the Cosmetic Directive. With the introduction of the new Cosmetic Regulation means the EU is moving towards a more robust, internationally recognised regime, which reinforces product safety taking into consideration the latest technological developments, including the possible use of nanomaterials in cosmetics. However, it must be noted that the Regulation is not due to be implemented until 2013, which makes the existing EU Cosmetics Directive still applicable.

In the USA, the expanding cosmetics industry after World War I brought about many safety concerns as more products became available on the market. In 1906, the Food and Drug Act was enacted but did not regulate cosmetics. It was said that the 1906 Act lacked control in regulating injurious cosmetics due to the inability to fit cosmetics within the definition of drug. As cosmetic injuries from cosmetic ingredients became known, the issue of regulation entered the political arena. In 1933, Tugwell Bill was introduced that included the regulation of cosmetics under the FDA. The proposal cited some tragic injuries resulting from cosmetics. The Bill, however, was opposed by the opposition. In 1935, due to increasing number of cosmetic injuries, President Roosevelt declared that more vigilant enforcement was required. Finally, despite many obstacles, in 1938, cosmetics were included in legislation, namely, the Federal Food Drug and Cosmetic Act of 1938. However, despite the introduction of the law, cosmetics in the USA are under the self-regulation of the cosmetics industry, which remains essentially the same to the present day.

Comparing it with the other two jurisdictions, Malaysia is considered the newest to introduce cosmetic regulation. In Malaysia, the law that governs cosmetic

58Directive 76/768/EEC, Article 2
59Regulation 1223/2209/EEC
61There was a changing of social view after the war where the younger generations began demanding cosmetics, as by 1915 it was noted $50 million dollars as the annual sales for cosmetics. See G. Kay, Supra, 2005, in chapter 2. Also, see Termini and Tressler, ‘American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety Regulations and Future Direction,’ Food and Drug Law Journal, Volume 63, Issue 1, 2008, Washington DC, Food and Drug Law Institute, p. 258.
products is the Control of Drugs and Cosmetic Regulations 1984. The law required that before cosmetics were placed on the market, they needed to be registered. Being a member of ASEAN, in 2003, ASEAN countries agreed to harmonise their cosmetic regulations and to adapt the EU Cosmetics Directive. As a result, a new regulation was introduced in Malaysia which was fully implemented in 2008. Before the introduction of the new system, the control of cosmetic products was through a prior approval system by the regulatory authority before the product could be released for consumers in the country. The system has been replaced by a notification scheme which means that cosmetic registration system is no longer applicable. The current development is said to accommodate safety and quality of cosmetic more efficiently.

1.6 Summary of the differences between the EU, Malaysia and the USA

The main idea of this thesis is to make comparisons between the EU, the USA and Malaysia in regards to the safety regulation for cosmetic products. In all three jurisdictions, cosmetic are subject to regulatory controls. Whereas the EU and the USA are among the largest markets of cosmetics in the world, the Malaysian market, although growing, is considerably smaller. Both the EU and Malaysia use control on safety of cosmetics by public regulations while the USA is renowned for its self-regulatory scheme on control over such products. Albeit different approaches, the primary purpose of cosmetic regulation in these jurisdictions is similar, that is; to ensure the safety of cosmetic products and to avoid adverse effects on consumer health. A closer examination of comparisons between these three jurisdictions demonstrates that all have recognized the importance of cosmetics safety but each of them has approached its implementation in a different way. It should be noted that the significant differences are mainly between the EU and Malaysian systems on the one hand and the American system on the other. This is due to the fact that, being a

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62See the details of comparisons in Chapter 6.  
member of ASEAN, Malaysia has modelled its law on the EU Cosmetics Directive, which is adapted by ASEAN and transposed by Malaysia into its guidance document, namely, Guidelines for Control of Cosmetics 2009. Nevertheless, there are also differences as far as procedures of implementation is concerned between Malaysia and EU, which will be specifically addressed in the comparative chapter.

All three jurisdictions share certain similarities. First, the responsibility for the safety of cosmetic products lies with manufacturers. It is the guiding principle, since, as the manufacturer they are the party that deals with the product from the very beginning of its formulation. The second similarity is that manufacturers of cosmetic in these jurisdictions do not require prior approval before marketing their products. Third, all of these jurisdictions also impose post-marketing obligations - activities that are aimed at the monitoring and surveillance of cosmetic products. For example, all of the jurisdictions carry out cosmetics recalls.

In comparing how cosmetics safety is regulated between public regulation and self-regulation, it can be seen that cosmetics firms marketing products in the countries that exercise public regulation, the EU and Malaysia, are under a heavier burden to verify that their products are safe. For example, cosmetics companies must conduct safety assessment tests and are not allowed to use certain chemical ingredients in their cosmetic formulations while such a requirement is only voluntary in the USA. In the EU, a scientific committee is given the authority to review the safety of cosmetics ingredients, this has also been adopted in Malaysia. There is however no statutory process for reviewing the safety of cosmetics ingredients in the USA; it is solely a voluntary process. Although the USA has a similar committee to review and assess the safety of ingredients used in cosmetics, its outputs have no legal authority and the FDA is not obliged to act on its findings.

The cosmetics safety regulations of the USA and those of the EU and Malaysia are also different in many other significant ways. Apart from the requirement to conduct safety assessments in the EU and Malaysia, cosmetics companies are also

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65 Directive 76/768/EEC.
66 ASEAN Cosmetic Directive (ACD).
67 These guidelines were prepared by Cosmetic Technical Working Group (CTWG), comprising of the National Pharmaceutical Control Bureau (NPCB) and representatives from the cosmetic industry. It was prepared in accordance to the ASEAN Cosmetic Directive and was published in May 2009.
68 Chapter 6.
69 Note that the registration system was applicable for cosmetics in Malaysia before the introduction of the ASEAN Cosmetic Directive. (See part II of Chapter 5 and part III of Chapter 6).
required to keep the product safety information compiled in a file which must be available for inspection upon a request by the local authorities. There is no such requirement in the USA. Labelling and warning requirements are also other point of differences between these jurisdictions. In the EU and Malaysia, cosmetics companies must label cosmetic products with a full ingredients declaration, expiration dates, function of the ingredients, instruction to be followed and batch numbers. In the USA, declaration of ingredients for cosmetics is also required by law. However, the other detailed labelling requirements are not as thorough as those imposed in the EU, such as the requirement to label an expiry date. In the USA, since cosmetic companies are not obliged to test their product before placing it on the market they are under obligation to warn the consumers indicating that their products have not been tested for safety. There are also differences of practice regarding surveillance activities in the USA with that of the EU and Malaysia, especially in the post marketing practices. All of these will be analysed in each national chapter as well as the comparative chapter in this thesis.

Since Malaysia has followed the EU in the way it regulates the safety of cosmetics, there are many similarities especially with regard to the safety principles used. All cosmetic products placed on the market are subject to pre-market control; such as the control of ingredients as well as the requirement to undergo a thorough safety assessment by an appointed safety assessor. Subsequent to the pre-market, there are also post market activities where companies and competent authorities monitor the actual safety of products on the market. There are however, certain differences; especially as far as the procedure of implementation are concerned. For example the practises of product notification and ‘audit priority’ for all whitening products in Malaysia. These differences are further explained in the comparative chapter.

1.7 The Global Regulatory Harmonisation of Cosmetics
Having different systems of regulation has created problems for countries wishing to promote their products in other markets. The differences in registration, safety testing, composition, and permitted ingredients mean that a business could not

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70 Drug Control Authority Newsletter, Volume 52, No 30, June 2011, on the cancellation of a whitening product notification by the NPCB due to adulteration with mercury.
export their products to other countries without having to undergo onerous procedures and pay high costs.\textsuperscript{71} Therefore, variations in cosmetics regulations undoubtedly affect international trade and the creation of a global market. Such variations also impact on the degree of safety provided to consumers within different countries and has resulted in barriers to trade. Although it may be claimed that such measures are there to ensure safety, consumers suffer due to a limited choice of products. A system of harmonised standards combined with mutual recognition is, thus, seen as a move to remove these barriers. The thrust behind harmonisation principles is that governments and industry have a joint responsibility to ensure that products are safe and effective when they reach the consumer. More importantly, it also encourages a more efficient industry, one that takes full responsibility for the safety of its products. Consumers enjoy more choice and manufacturers are not burdened by the trade barriers. The EU is the first region that moved forward to embrace harmonisation. Through the regulatory harmonisation of the cosmetics regulations, the EU, now with 27 member states, set aside the differences of cosmetics regulations in each member country to reach a mutual standard that assists the cosmetics trade, and, at the same time, increases the safety of consumers.

The members of the Association of Southeast Asian Nations or ASEAN\textsuperscript{72} have followed the trend of globalisation by integrating their own cosmetics regulations. Malaysia, being one of the original ASEAN members, embraced this harmonisation because of the problem of the influx of unsafe cosmetics. Many cosmetic products had previously been found to contain harmful substances\textsuperscript{73} in their formulations. This was especially the case with whitening products.\textsuperscript{74} In addition, there were also problems of counterfeit cosmetic products flooding the market. Consequently, ASEAN decided that in order to provide a better standard of safety for cosmetic products, the product standard eventually needed to be harmonised. The most significant aspect of the harmonised scheme is that the ASEAN Cosmetics Directive (ACD) takes its essence by adopting the European Union’s Cosmetics Directive

\textsuperscript{72}ASEAN or Association of South East Asian Nations consists of 10 member countries – Malaysia, Indonesia, Singapore, the Philippines, Vietnam, Thailand, Laos, Cambodia, Brunei and Myanmar.
\textsuperscript{73}See footnote 38 and 70 earlier
\textsuperscript{74}Footnote 37 earlier. In Malaysia for example, whitening products when they are sent for product sampling to the cosmetic authority, they will be treated as ‘priority products’ as there is a possibility of the adulteration of such products with hydroquinone and tretinoin. This is based on the information provided by officer of the Cosmetic Unit, NPCB, Malaysia dated 29 March 2011.
(EUCD). Adapted from the EU cosmetic framework, the EU has assisted ASEAN to develop the Cosmetics Directive, which has been implemented by ASEAN member states, including Malaysia. Under the ACD, ASEAN regulators and the cosmetics industry have decided on common standards for cosmetic products as well as standardising rules for safety testing and cosmetic marketing. The ACD limits restrictions on the trade of cosmetic products by streamlining technical controls, promoting mutual recognition in terms of product registration, and establishing a coordinated market surveillance system to ensure that the safety, quality and claimed benefits of cosmetic products sold to the consumers are of the same standard. This has been the effect of the global cosmetics harmonisation that has taken place - both in the EU and ASEAN. The harmonisation of cosmetics regulation will also be discussed in the Malaysian chapter.

1.8 Objectives of the study

The objectives of the study are:-

1) To examine the significance and justification for the chosen area of study, that is, the cosmetic products safety regulations, and to discuss the background issues of cosmetics safety.

2) To examine the essential elements that underpin the product safety regulations by identifying the pre-market and post-market controls - that are the techniques used in safeguarding the safety mechanism.

3) To analyse the EU’s practice/scheme in its regulation of cosmetics safety.

4) To evaluate the USA’s considerations in controlling the safety of cosmetic products and the efficiency of its self-regulation mechanism for cosmetic products.

5) To study Malaysia’s considerations in the current cosmetic safety mechanism, which model it has adopted and why.

6) To analyse in detail the comparative aspects of cosmetics safety regulations in the three different mentioned jurisdictions by looking at their differences and similarities and determining which one is best at regulating the safety of cosmetics.

7) To examine what safety regulations are most suitable for the newly emerging technology used in cosmetic products that is, nanotechnology. Are the existing regulations adequate for this new technology?

75 The ASEAN Cosmetics Directive has been transposed into Guidelines for Control of Cosmetic Products 2009.
1.9 Limitations of the study

As mentioned earlier, this study will be confined to product safety regulations concerning cosmetic products. This thesis is not the place for detailed analysis of private law, in particular product liability rules, to protect consumers. Some of brief comments, are, however made in order to permit an insight into the perspective from which the thesis is approached.

There are many other interesting issues under cosmetics regulations that have taken place, it is reasonably clear that space and time do not allow everything to be covered within one thesis. Therefore, various matters are not covered in this analysis. The study only discusses the regulations underpinning cosmetics safety in the three mentioned jurisdictions. This thesis is not intended to cover the historical development of cosmetics legislation; however, some background to the cosmetics regime will be mentioned. This study is also restricted to the regulation of cosmetics alone and not other products. However, some comparisons with pharmaceutical products are mentioned to determine where cosmetics stand in the larger picture of general safety regulations. In addition, this study does not go beyond the safety issues of cosmetics but concentrates on the regulation of cosmetics.

The researcher does not intend to include the other topics currently being debated in cosmetics, such as advertising, labelling, animal testing- although there are undoubtedly some interesting developments in the said areas, and they merit separate studies. It is also noted, with regards to the study on Malaysia, that one of the limitations is the lack of materials and previous work on the study of product safety regulation, cosmetics safety regulation as well as nano-cosmetics in particular, as it is a new area in Malaysia. Furthermore in this jurisdiction most of the information which is very relevant to the study but relates to government policies is confidential and not accessible to the public.

1.10 Research methodology

Comparative law has purposely been chosen as the method for this research since it is the best way to analyse one’s own system, and in fact there is no better way for any
hypothesis or theory to be tested than through comparison with others.\textsuperscript{76} As Lepaulle pointed out:

“to see things in their true light we must see them from a certain distance as strangers, which is impossible when we are studying phenomenon of our own country. That is why comparative law should be one of the necessary elements in the training of all those who are to shape society.\textsuperscript{77}”

Comparative law methodology is essential and inevitable in any research on product safety law, in particular, cosmetic safety regulations, for at least two reasons. Firstly; the subject has international dimensions since there has been a trend of globalization and harmonization of cosmetic regulation, the astounding sales due to beauty trends in consumer perspectives, and the changing of cosmetic systems that have occurred in different parts of the world. Secondly, there are growing reports concerning the hazardous substances in cosmetics, which sometimes can be underestimated. Thus the approach throughout the study is to maintain two methods of comparison:

(1) Comparison between different types of rules of law which are applicable to cosmetic safety regulation;
(2) Comparison between different contexts of safety procedures and implementation, based on the different types of law as above, by looking at the social, cultural and economic environment in which each jurisdiction (the EU, the USA and Malaysia) operates.

The position in Malaysia needs to be compared with the EU for the obvious reason that the new cosmetic safety regulations in Malaysia is taken from the EU law and it seems likely that future legal developments in the country, particularly in the area of nano-cosmetics, will also be influenced by the development in the EU.

Glendon\textsuperscript{78} commented that there is not an established methodology for comparative law research and there is a dearth of scholarship on the subject. Thus, in this thesis, some thought has been taken over the correct approach, and a jurisdictional one has been chosen. The advantage of this approach is that it is very

\textsuperscript{77} Lepaulle, 'The Functions of Comparative Law', 1922, 35 Harvard Law Review, p. 853
\textsuperscript{78} Mary Ann Glendon, et al, \textit{Comparative Legal Traditions In a Nutshell}, St. Paul: West, 1999, pp. 8-9
systematic and the reader will also be able to easily follow the discussions and comparisons. Second, it has been found that each jurisdiction compared in this thesis, has its own system and reasons for choosing its system. The USA, for example, is known for having a unique system for cosmetics that is self-regulatory – throughout its history it has relied on the cosmetics industry to regulate itself. While the EU, with a more elaborate and systematic approach, still has problems with the transposition processes for national countries. As for Malaysia, it is necessary to view it from the perspective of a developing country and because of this, it is essential to provide a specific discussion and to explain why there has been a legal transplant and what form it has taken. All these must be addressed separately to appreciate the differences and similarities (if any), as well as to consider the separate legal issues that have come to light, as far as the cosmetics safety regime is concerned. Third, there is a comparative chapter that specifically addresses the differences and similarities, which not only summarises these but considers the underlying principles and analysis behind them. It has been stated by Venter that:

“we are drawing information from different systems for the purpose of improving our understanding of law be it foreign or local.”

Thus, it is submitted that having this comparison helps in understanding how cosmetic safety being addressed in a country. Also, particularly for Malaysia, by looking at other systems, it helps find what more are needed to improve its system, to achieve better safety protection for the consumers.

In carrying out this comparative research, a qualitative approach is the most appropriate method. For the purpose of carrying out this method, data or document analysis and informal interviews were chosen.

a) Document analysis
Document analysis in this particular study involved searching for and identifying legislation, i.e., cosmetics regulations and the pattern of cosmetics regulations in the three different jurisdictions, namely, the USA, the EU and Malaysia. There are two types of sources in this data analysis, primary and secondary sources. The primary

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sources are the sources that are obtained from the laws and statutes, guidelines, comments and consultation documents (especially in the EU for the EU Cosmetic Regulation), report of survey, textbooks, articles, etc. The secondary sources are the sources that are taken from newspaper articles, media coverage, bulletins, and opinions/comments from the informal discussions with interviewees.

b) Informal discussions
Another method employed in this research to collect materials was by having informal discussions with government officials and industry representatives. It must be emphasised that having such discussions was not a primary method for collecting data. Instead, it was carried out to complement data that has been obtained through document analysis. In other words, the main research method of this study is still document analysis. As legal research has been transformed by the easy access to vast databases of online materials, this is certainly the case for the EU and the USA. Many relevant materials are readily available, either from online databases or from library searches. In addition, several journals have provided extensive and comprehensive material concerning safety regulations in these jurisdictions. However, this is not the case in Malaysia. The ACD was only introduced very recently and because of this relevant materials on online databases are very limited. Although there are some materials published online regarding the harmonisation of cosmetics regulations in ASEAN, there is a lack of academic discussion concerning the implementation of the new regulations in Malaysia. This has resulted in a difficulty in finding information and collecting data. While doing a comparative study of the three different jurisdictions, the relevant data collected needs to be balanced and of an appropriate amount concerning the particular issue addressed. It is, however, very difficult to do this when only two of the jurisdictions have adequate materials whilst the other jurisdiction does not. This would result in an imbalance concerning comparative aspects and, this study would ultimately fail to meet the objectives of the research. Consequently, to provide more reliable data for the comparative study, informal discussions were had for the Malaysian part to achieve an in-depth understanding of how the regulations have been applied. Informal discussions have been had with officials in the Cosmetic Unit, National Pharmaceutical Control Bureau Malaysia, the enforcement officers as well as a safety assessor who works with the cosmetics industry, and a director of a nanotechnology agency to provide insights into the
implementation of the new regulation in Malaysia. In short, it is important to understand significant developments in legislation that have been passed as well as the actual implementation of it.

1.11 Outline of chapters
Chapter 1 has contained the general introduction of the study and is divided into nine sections. These are: the background to the study, the need for product safety, significance of the study, objectives of the research, scope and limitations, methodology applied, and chapter outlines. Harmonisation is also explained in this chapter, aiming to illustrate the pace of change in the cosmetics industry due to globalisation.

Chapter 2 is divided into three parts. The first part examines the main principles underpinning consumer protection by way of the regulations concerning product safety. In a market where consumer goods are increasing in complexity and sophistication, consumers are unable to anticipate risks and safeguard themselves, thus, resulting in an urgent need for government intervention in the marketplace for consumers who need protection. Here, theory on what makes a good safety regime is discussed. It appears that a good safety regime requires a regulatory framework where safety is the direct responsibility of the manufacturer, and where authorities are in charge of pre-market control. In addition, standardised labelling, providing full transparency of information to the consumers is extensive for the majority of products (information regulation). Risk assessment is also important, especially in modern products where the chemicals are used in the product formulations. Lastly, the role of the precautionary principle precept is also highlighted under this part. Part II then goes further, discussing the specific techniques of the safety regulation where the most common distinction in product safety regulation is usually between pre-market and post-market controls. As cosmetics are the specific products chosen to be discussed under the safety regime, it is therefore relevant to put them into perspective relating to safety regulations more generally. Part III contains discussions on what type of products cosmetics are and what type of regulation best suits cosmetics safety.

Chapter 3: Following the understanding of the theoretical framework of the safety regulations, the discussion then explores the current issues further and debates on cosmetics safety in the chosen jurisdictions. This chapter starts with the
EU by assessing the considerations of the current/existing framework that has become part of the practice and criteria of the EU’s cosmetics safety. The historical background for the introduction of the EU Cosmetic Directive is discussed, and there is an analysis of the cosmetics safety framework focussing on pre-market and post-market controls. Lastly, there is a discussion on the issues and debates that surround the way the Directive is put into practice.

Chapter 4 looks at the USA’s cosmetics safety mechanism, which is well-known for its self-regulation and its many differences to the EU. First, there will be a description of the history and early background of its cosmetics industry, including some examples of the injuries relating to cosmetics. The second part will discuss how cosmetics safety is guarded in the USA through industry self-regulation. This scheme, based on self-regulation, is not without critics. Part III deals with these criticisms.

Chapter 5 analyses the Malaysian implementation of cosmetics safety regulations, being a member of ASEAN, there is an introduction regarding the ASEAN Cosmetics Directive in Malaysia. This is followed by a discussion about the way the safety system changed once the Directive was put in place. Part III examines the issues and challenges that have surfaced, and some recommendations are made which it is hoped will improve the new system.

Chapter 6 gives the comparative analysis of the three jurisdictions. This chapter is divided into three parts. Part I deals with issues including- the different definitions of cosmetics, the pre-market regulatory scheme such as the control of ingredients used in cosmetic products, notification or product registrations and the safety standards for cosmetics, labelling requirements, and the post marketing activities to control cosmetics after they are released on the market. Part II discusses the pros and cons of cosmetics registration (prior approval) and cosmetics notification in Malaysia. Part III concludes an analysis of which jurisdiction has the most efficient system for regulating/controlling the safety for cosmetic products - public regulation or self-regulation?

Chapter 7 analyses the new technology that has appeared on the market and that is being used in many consumer products including cosmetics. While nanotechnology is now widely used in cosmetics, its safety is still being debated. Clearly, such new products need to be assessed in a similar or even a greater way to ensure the safety to consumers. At the moment it is observed that the USA decided to maintain its status quo, that is, to regulate nano-cosmetic as other traditional
cosmetics, while for the EU, the nano provisions have already been included in the EU Cosmetics Regulation which is scheduled to be implemented in July 2013. For Malaysia, despite it adopting the EU approach by virtue of being a member of ASEAN, it is yet to decide whether to adopt the new regulation, as it is still in the discussion process. Despite the fact that nanotechnology is reckoned to bring benefits, it must be balanced with any adverse effects, which is why regulation is necessary.

Chapter 8 is the concluding chapter, which summarises the principal aims of cosmetics safety regulations in the three analysed jurisdictions and whether the aims of these have been achieved. This thesis has found that all of the jurisdictions compared have addressed the safety of cosmetics products in their own way. Primary reliance on government regulation is thought to offer greater cosmetics safety compared to self regulation. Through direct involvement, the EU has the most comprehensive and adequately systematised scheme. This explains why Malaysia (being the member of ASEAN) has used the EU Cosmetics Directive as its model. As this thesis also examines the shift of Malaysia’s cosmetics regulatory system from prior approval to cosmetics notification, this thesis has shown that prior approval on cosmetics can be very restrictive and is therefore no longer suitable to be used on such products. Although still new and despite teething problems and more improvements needed particularly in terms of enforcement, the change in Malaysia’s cosmetics system can be regarded as a success and has significant advantages. Lastly, with regard to regulating the safety of the use of nanotechnology in cosmetics, despite a good deal of research, there is still very much uncertainty that the current framework is adequate.
Chapter 2: The Theoretical Aspects of Product Safety Regulation

2.1 Introduction

The need for product safety regulation is no longer a source of controversy.\(^{80}\) There is a large body of academic work that has addressed the theoretical justification for such regulation; mostly covering economic and sociological justification.\(^{81}\) The most cited reasons for product safety regulation are the market failures that occur in conjunction with private law failures.\(^{82}\) Product safety regulation is a government's attempt to ensure that only safe products are produced and sold to consumers. Such a role is also being performed by private law through the imposition of product liability, an area that has developed over time to protect consumers. As the main objective of product liability is compensation, the law seeks to provide redress for damage suffered by the victim of defective products and thus it may be seen as part of the solution to the problem of unsafe products. Another rationale for product liability rules is to create incentives for producers to manufacture safe products.

Although both are considered to be similar by some\(^{83}\) because they seek to minimize accidents, product liability is actually very different from product safety. The two adopt different functions. Product safety seeks to establish which products should be free to be circulated on the market. Once in circulation it is inevitable that some of those products will cause damage. This is because product safety cannot eliminate the dangers posed by products entirely, but merely decide what level of risk is acceptable. There is also the issue of defects to products caused by their poor manufacture or their damage in transit. When this damage occurs, the function of product liability is then to determine whether losses can be compensated. In other words, product safety is the term used to describe the regulatory control by

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\(^{81}\) The discussion on those justifications is provided in the next section. Some writers also cite political influence over regulation, see Peltzman, ‘Towards a More General Theory of Regulation,’ *Journal of Economics and Law*, 19, 1976, pp. 211-240. This has also been analysed by C. Hodges, *European Regulation of Consumer Product Safety*, 2005, p. 12.

\(^{82}\) Further discussions on the justifications for government intervention is in Part II of this chapter.

governmental authorities of the marketing of products through legislation and consequently functions as a preventative measure.

Therefore, both sets of laws complement each other when it comes to providing effective solutions to problems concerning harmful and defective products. However, as mentioned in the previous chapter, the present study only concerns itself with the theoretical aspects of product safety regulations in relation to cosmetics.

This chapter is divided into three parts. Part I begins with commentary on the limitations of private law in safety regulation, before going on to consider the need for safety regulation. It is very important to introduce the discussion by illuminating the reasons for having safety regulations in general. The discussion on product safety regulation usually involves pre-marketing and post-marketing obligations. These will be examined in part II. Part III then focuses on the pertinent characteristics of safety regulations where certain concepts of the existing theory are adopted for cosmetics in the analysis of safety issues. This chapter concludes with a discussion on the type of products cosmetics are and the type of regulation that best suits the safety of cosmetics.

2.2 Part I: Product Liability: Its Role and Limitations

By comparing product safety and product liability, it is possible to see that product liability is a more popular research topic in terms of comparative law research especially in the USA\(^84\) and the European\(^85\) systems. It is understandable because, as Howells\(^86\) sees it is easy and interesting to track how legal systems have, within a relatively short space of time, reacted to the new topic of product liability.\(^87\) However, it can be said that product liability suffers some limitations in that it does not provide adequate protection to ensure that only safe products are placed on the market. The potential risk of a product, in other words, is not solely guarded by reliance on product liability.

\(^84\)In the USA, product liability is a course in its own right. For example, product liability has its own courses in the law school curriculum, its own textbook and treaties, and numerous American lawyers make their living from product liability litigations. See G. Howells, 1998, supra, p. 306.
\(^85\)In contrast, in the EU, product liability is only taught as part of torts/obligation courses or as a topic in consumer law courses and it only remained a minor area of practice, op.cit.
\(^87\)Ibid., p. 306.
Cartwright\textsuperscript{88} establishes four limitations of private law, the first is that private law depends for its enforcement on the injured party taking action; however, the enforcement costs of bringing an action often mean that many breaches of the law will go uncorrected.\textsuperscript{89} The possibility to bring civil actions will not satisfactorily prevent the manufacture and supply of dangerous products.\textsuperscript{90} Therefore, this is hardly a deterrent to those manufacturers as usually the amounts claimed are relatively small. Secondly, private law focuses primarily upon correcting harm that has already taken place by way of providing compensation. It is important that where a product is of potential hazard to consumers, preventative measures are taken to prevent such products from reaching the public. Private law only addresses the problem \textit{after} the harm has occurred. It does not directly prevent dangerous products reaching the market and preventing the harm from occurring. Although it may seem that there are some deterrent effects in the future for wrongdoers, however if the person \textit{‘hopes to avoid any sanction and is probably little worried by the prospect of having to make reimbursement or an effective payment,’} \textsuperscript{91} it might seem that such a deterrent effect might not deter the people as it is supposed to. It must be remembered that consumer protection should not ideally be left in the hands of individual consumers taking action after the harm has already been done. In other words, prevention is always better than reparation.

Thirdly, according to Cartwright, sometimes there can be problems of external costs that might be suffered by third parties in private law transactions. This is known as externalities. Ogus\textsuperscript{92} is of the opinion that often externalities are present in private law transactions. Persons other than the purchaser may consume or use the product; but some of the consequences of the unsafe or dangerous products may be borne by other third parties. Even though the law of tort can provide some limit of protection, it is still inadequate in the sense that it allows dangerous products to be sold on the condition that compensation is paid in the event that they cause injury.\textsuperscript{93}

\textsuperscript{89}\textit{Ibid}, p. 698.
\textsuperscript{90}\textit{Ibid}, p. 699.
\textsuperscript{93}The discussion on externalities is in the next section.
Fourthly, although some rectification can be made through the law of contract, as far as the law of contract is concerned, such law is hindered by the rule of *privity*. This rule means that nobody outside the contractual agreement is allowed to bring action against the party to the contract, even if she/he is injured because of that contract. Even though this imperfect doctrine has been strongly criticized for being unfair and some developments have taken place to make it easier for a third party to sue in limited circumstances, this doctrine is still available and largely applicable.

Some argue for the use of tort law to provide some amount of safety, as is evident in the USA where ease of access to justice in personal injury cases combines with high damage awards including punitive damage to make manufacturers produce safer products. However it is also an *ex post* mechanism, and apart from being considered the most expensive method, (because of high transactions and administrative costs, including legal fees) it is not efficient if damages are imposed on large numbers of people and where a person/company that caused injuries is too poor to pay for the harm they have caused. However if the company can get insurance then the risk of people going uncompensated is removed, but it also means the deterrent effect is reduced. Also, although there have been debates about the appropriateness of using criminal law in consumer protection and there are administrative rules as an alternative, criminal sanctions have a role in controlling dangerous products. Furthermore, it could be argued that the criminal law which prohibits the sale of dangerous products are examples of regulatory offences and that such crimes are ‘not criminal in any real sense.’

Based on the above reasons and limitations, private law has not produced a perfect solution. Although it can be argued that civil cases concerning consumer products are more likely to be successful than criminal actions, (as the legislation

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95It is a traditional doctrine which is considered unfair as it allows only parties to a contract can enforce it. In other words, no one except a party to a contract can acquire rights under it, and similarly no one except a party to that contract can be subjected to liabilities under it.


99Ibid.
imposes strict liability), and in criminal law there is a higher burden of proof and the supplier may be able to make a defence of 'due diligence' which is particularly relevant when the issue is one of quality control rather than product design, the consumers should not be expected to rely upon private law for their protection.

Therefore, an additional regulatory control which is based on regulation of public law should be in place. In addition, even though it is the producer or manufacturer who may suffer financially, ultimately it is the injured consumer who suffers the physical harm. A special regime is needed to provide specific control for the protection of consumer safety that prevents harmful goods from reaching the market as well as providing post-marketing functions such as surveillance and monitoring. Such protection is provided under the regulation of product safety.

2.3 The Need for Product Safety Regulation

Both product safety and product liability complement each other. According to Calabresi, both product safety regulation and product liability are the branches of law whose goal is the minimisation of accidents while Shavell points out that a joint use of liability and safety regulation are 'socially advantageous' and could be the solution to control the risk. According to him, it is because, 'parties are required to satisfy a regulatory standard and are likely to face possible liability.'

It should be reiterated that product safety regulation is aimed at preventing dangerous products from reaching consumers. This may require some products to be banned or their content controlled, however, equally, it is important to inform users about potential risks and informing them how to use products safely and as intended. This is especially so as the use of chemical substances in modern consumer products is on the increase, including in cosmetic products. Ash, one of the main cited authors on the economic perspective of product safety regulation, contends that the controversy over public regulation of consumer safety is in some aspects similar

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100 Instead of negligence on the part of the producer, it is only necessary to show that ‘...the safety of the product is not such as persons generally are entitled to expect.’ See Hayward, G, ‘Helping Judges Judge Safety,’ Solicitors Journal, EW Supp, 11 Dec 1998, pp. 22-26.
104 Further discussions is provided in the next section
105 Asch, Peter, Safety Regulation, 1988, Oxford University Press.
to other debates about the role of governments. He identifies two groups; the proponents of safety regulations whom he terms ‘regulation advocates’ and the ‘traditionalists’ those who oppose them. According to him, the consumer advocates have regularly asserted a ‘right to safety’ and argued that private market, left to its own devices, will impose unacceptable risks on the public.

The traditionalists, on the other hand, counterclaim that, in specific instances, public intervention ‘has been undertaken without adequate analysis of its consequences.’ The reason that has always been cited for the merits of this regulation is the reduction of accident and injury statistics. With regards to accidents/injuries, it is common that data from accidents are collected, the seriousness of injuries are recorded, samples are taken and so on. However, it is still argued that even though such data and statistics have been taken, it is still not possible to draw an accurate conclusion on how dangerous products are. Joerges argues that this is because sometimes the circumstances and the causes of accidents are extraordinarily complex and also because of the characteristics of the products themselves.

With many more complex products on the market today, the potential risks are increasing. Therefore, product safety regulation also needs to cover a wide variety of potential safety risks. The rules are generally directed at the producers and distributors in order to influence the manner in which products are marketed and manufactured. Pre-marketing obligations are one of the important regulatory controls deployed under the product safety regulations that are able to control the potential risks. This type of obligation includes prior approval which is normally done through licensing requirements and also rules which determine standards. Apart from pre-marketing, product safety regulation also requires a post-marketing dimension covering the notification, withdrawal and recall of products that are found to be unsafe. Generally the post marketing obligations are concerned with monitoring products in the market place and ensuring that action can be taken once the dangers are traced. They are also directed at producers and distributors, including of course, retailers.

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106 See further Asch’s discussions, ibid, p. 7.
108 Ibid., same page, also mentioned in the preface page.
110 C. Joerges, op.cit., 2010, p. 120.
Information regulation is another important instrument that is significant under product safety regulation. Information regulation is regarded as a ‘smart’ option as it preserves consumer choice, improves competition among firms and does not include technical rigidity which may be caused by product standards.\textsuperscript{111} In short, product safety mechanisms help to create an atmosphere where producers take responsibility themselves for not only producing their products but also for monitoring and reacting to dangers. The law indeed plays a role by imposing requirements on producers to create procedures to detect and react to concerns about their products.\textsuperscript{112}

In the EU, product safety is regulated under the General Product Safety Directive (GPSD).\textsuperscript{113} The USA has the Consumer Product Safety Act 1972\textsuperscript{114} (CPSA) and the responsible agency is the Consumer Product Safety Commission (CPSC). Malaysia has no general law and agency that covers product safety specifically, instead the Consumer Protection Act 1999, Part III holds special provisos as far as product safety is concerned.

2.3.1 Government intervention

There is extensive academic work\textsuperscript{115} on the theories of regulation. The most common aspects of safety regulation that have been analysed are the economic\textsuperscript{116} and sociological\textsuperscript{117} ones, both as general theory and in specific market examples.\textsuperscript{118} For some others, political influence is also cited as part of safety regulation.\textsuperscript{119} Regulation is always well understood as an instrument of economic and industrial policy, acting

\textsuperscript{111}Arcuri, 1999, supra, p. 1.
\textsuperscript{112}The example can be seen is in the EU, as its General Product Safety Directive(GPSD) imposes post-marketing monitoring obligations on producers and distributors, while in the USA, there are significant obligations to notify potential dangers to the Consumer Product Safety Commission (CPSC).
\textsuperscript{113}Directive 2001/95/EC, applicable from 15 January 2004
\textsuperscript{117}Ogus, 2004, supra. Also see I. Ayres and J. Braithwaite, Responsive Regulation-Transcending the Deregulation Debate, 1992, Oxford.
\textsuperscript{119}For example, S. Pelzman argues that regulatory outcomes are determined by political equilibrium, the balance of opposing interests, depending on organizational costs faced by competing groups. See further S. Pelzman, 'Towards a More General Theory of Regulation,' Journal of Economics and Law, 19, 1976, pp. 211-240, see also Wilson (ed.), The Politics of Regulation, 1980, New York.
especially through the mechanism of ensuring a competitive market. In terms of economic arguments, the classic reason for the intervention by a government is in order to remedy market failures such as anti-competitive behaviour or asymmetry of information or a failure to provide an adequate level of consumer protection. Government intervention has been regarded by some scholars as necessary in order to protect consumers from harmful products flooding the market.

Viscusi however asserts that governments should not intervene in regulating product safety except where there is established evidence that there has been a market failure to provide a reasonable level of safety. Howells points out that government intervention usually lack technical knowledge and tend to be more responsive to industry than consumer concerns. He further explains that one of the problems with regulating consumer products is the sheer number of different types of product concerned.

What should be remembered is that consumers have the right to expect products to be safe and free from hazards and defects for the life of the product and its intended use. At the very least, consumers have the right to be protected from preventable risks. For certain products such as cosmetics, their quality can only be ascertained through consumption. Sellers will generally have superior information regarding these matters. Furthermore, different types of products require different levels of regulation; for example much more stringent laws including prior approval are needed for pharmaceutical products. Whereas there are other products that only need to fulfil standard requirements or simple notification to the authorities before placing on the market.

2.3.2 Characteristics considered for product safety regulation

Earlier it was mentioned that government intervention, through product regulation is necessary and justified as consumers should not have to trust to private decisions to guarantee the safety of the market place. However, product regulation does not

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120 See Hancher, *op.cit.*, 1990. Also see Ogus, *supra.*
124 Ibid.
126 This will be dealt later in Part II of this chapter.
mean the production of risk free products; it is about ensuring products only represent acceptable risks. Also, product regulation cannot be expected to regulate for risks which are unknowable at the time of marketing. Product regulation will still lead to products being marketed which will pose dangers to consumers, however consideration of some characteristics could help make the risks acceptable. As new products are brought out everyday, the fact that they are very sophisticated and complex makes it difficult for consumers to gauge their safety, quality and efficiency. Nowadays, increasing consumer demand for products that possess enhanced aesthetic and functional qualities, including products that ‘renew, restore, and rejuvenate’ has resulted in an ever growing interest in the cosmetic industry. This section will discuss the purpose and nature of each characteristic that are considered key points in the general product safety mechanism: they are the information regulation, the assessment of risk, the responsibility placed on the manufacturer and producer of a product and lastly the precautionary principle. Part III will specifically discuss the relationship of these characteristics with cosmetic safety.

### 2.3.2.1. Information Regulation

In product safety regulations, information regulation is regarded as one of the most essential elements. Cartwright describes information regulation as one of the most commonly used regulatory techniques in the consumer protection area. It is regarded as ‘less interventionist’ in character compared to many other forms of regulation. As explained previously, regulatory intervention through information regulation would not be necessary if consumers had the full information on the characteristics of products offered in the market and if externalities does not exist in their purchasing decision. However, as with many consumer products, conditions of information deficit and externalities do exist. Insisting that information be disclosed in some cases can be a solution to product safety problems. For example, if someone is allergic to nuts, then harm can be avoided if a product containing nuts is labelled conspicuously. Similarly, warnings of product risks are important if they are deemed to be an acceptable characteristic of the product. This is based on the fact

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127 Howells, *supra*, 1998, p. 6
130 See footnote 17 in the earlier chapter on externalities.
that a warning can help consumers take steps to avoid potential danger - as without any information being provided to them, it is difficult for the consumer to know and understand which products contain what ingredients, and how they can be used so as not to cause them harm. Ash contends that consumers are usually assumed to know the characteristics of the goods they buy; however what must be noted is that it is not equivalent to knowing with certainty how a particular product will perform, and how safe it is. Where there is a lack of information either because it is unavailable or available but costly, decisions often become more complicated. Also, the consumer might get the answer from ingredients labelled on the packaging but it is still possible that the consumer might have problems in absorbing the disclosed information.

Consumers normally have less information than traders; therefore often they have difficulty in making decisions that reflect their preferences. This is what is called information asymmetry, as explained earlier. Akerlof, among others, has pointed out that asymmetries in information are likely to impede efficiency and may even preclude the existence of viable markets in extreme instances. While information asymmetries are cited somewhat as a hindrance for a 'perfect market,' Howells emphasises the insights provided by behavioural economics which suggest that consumers may not always respond to information provided as reasonably as traditional economic models sometimes believe. Since there are not sufficient incentives for traders to volunteer information, the law needs to require that the information is provided. Once the information is provided, consumers can protect their own interests by selecting goods and services closest to their preferences. Ensuring choices are made based on reliable information can help reduce potential harm.

In general, under the safety regime, manufacturers have a responsibility to ensure the safety of the products they develop and sell to consumers and to make sure that relevant information reaches the consumer together with the products.

132Ibid.
134One of the illustrations given by Akerlof of asymmetric information is the market for used cars, where sellers have a far better idea than buyers of whether a used car is good or a 'lemon' with the expected result that lemons dominate the market.
136See section Responsibility for Product Safety.
Producers must provide consumers with relevant information, for example, warnings labels and instructions which will help consumers make their own risk assessments and choose products accordingly.\textsuperscript{137} Also, it should be remembered that for the consumer to make the best decision, the information provided must also be in such a way that he can recognise and take notice of it. Otherwise if the information is not suitably supplied, it has the tendency to be ignored.

Even though it can be argued that manufacturers and producers have no incentive to produce harmful products because of product liability regulation\textsuperscript{138} and adverse publicity,\textsuperscript{139} if an unregulated market does not produce an optimal\textsuperscript{140} amount of information, consumers may sustain a welfare loss. Therefore, forcing the seller to supply that amount of information may eliminate the loss. This information requirement does, to an extent, restrict the freedom of the traders in so far as they are required to disclose information they may have preferred not to have revealed.

However, it can also be questioned whether the manufacturer or supplier of potentially hazardous products will be ‘brave’ enough to tell the consumers about the potential hazards the products posed? Hodges argues\textsuperscript{141} that a private market economy provides too little information about hazards. Other literature contends that a firm has no incentive to advertise the potential danger of its own products, especially when its competitors do not.\textsuperscript{142} Clearly it cannot make most manufacturers happy to tell consumers that their products may harm them.

**Warning and Instructions**

Many products are unsafe unless operated safely. Kessler\textsuperscript{143} points out although a product is not inherently harmful or defective however will be treated defective if its use could cause harm because of improper directions or inadequate warnings.

\textsuperscript{138}As discussed in earlier section
\textsuperscript{140}Optimal amount of information according to Ogus is where the marginal benefit arising from that amount of information is approximately equal to the marginal costs of producing and communicating it—see Ogus, *supra*, 2004, p. 121.
\textsuperscript{141}Hodges, *op.cit.*, 2005, Chapter 1: The theoretical aspects of regulation).
Dickerson is of the same view pointing out that if it is not feasible to improve the product's performance or provide safety device for a situations in which the consumers to be undesirably vulnerable, the answer may lie in requiring appropriate warning or instructions for use. Consumers can sometimes be persuaded to follow instructions if they are warned of the consequences of failing to do so. Appropriate rules on instructions for use are therefore a legitimate part of any regulatory regime. Warning and instructions are therefore needed. While 'instruction for use' is a direction given by the manufacturer on the proper use of a product, the warning is a cautionary statement or advice by the product’s manufacturer to the people who would otherwise not be aware of a potential or impending danger in a product or who might fail to follow the instruction or any other additional safety statement.

Warnings have, according to Cartwright, played an important part in product safety law. He further states that warnings are considered efficient, as they are a relatively cheap and simple way of bringing risks to the attention of the consumer. In other words, warnings favour consumers as according to Trebilcock, 'simple warnings, unlike bans, actually retain consumer choice, but do not have the information costs associated with more sophisticated disclosure devices.' Howells suggests that this approach will have a greater impact on consumer behaviour than pre-purchase information, 'which often goes over the heads of many consumers who are more interested in the benefits than the risks posed by products.' Improved information flows as suggested by Ogus can also generate indirect welfare gains for consumers by rendering the market more competitive. However, in some situations the information requirement is not adequate, as the efficiencies of warning in relation to product safety have been contested; Lucas and Hodges, both argue that changes to product design are likely to be far more effective than instructions and warnings.

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147Ibid., p. 529.
149Ibid., pp. 40-41.
150Ogus, supra, p. 122.
151Lucas, 'Warnings: Do They Really Make a Difference?' Safety and Health Practitioner 18, 17 (7), 1999.
2.3.2.2. Risk Assessment

In order to be specific about the level of safety that is required to be achieved, concepts of risk are used, as Lowrance has said ‘a thing is safe if its attendant risks are judged to be acceptable.’\textsuperscript{153} Every product safety regulatory regime must take into consideration the assessment of risk. Betton\textsuperscript{154} states that ‘risk is a product of the intrinsic properties of a material and degree of exposure.’ In fact, measuring risks is regarded as a science in itself. Risk, according to Hodges, is a concept based on quantification, and therefore, it is necessary to make a judgement on whether risk is present in any product as well as what level of risk in a product is acceptable.\textsuperscript{155}

There are different risks for different products.\textsuperscript{156} According to Hood, Rothstein and Baldwin,\textsuperscript{157} they argue that a workable control system must include certain mechanisms for example the collection of information, the setting of standard, and the modification of behaviour, not forgetting that there must be a clear relationship between these. Hodges argues that achieving coherent integration between design and operation of regulatory systems is often lacking.\textsuperscript{158} Determining risk is not easy especially when each and every product carries a different or distinct risk. The acceptability of risk might be based on the fact that it is doubted whether an admitted risk is likely to cause consumers more harm.\textsuperscript{159} Hodges maintains that risk is implied in the marketing and use of every product.\textsuperscript{160} Howells alleges that consumers may not attain their preferred balance of risk, because their decisions are frequently based on misconceptions about risk.\textsuperscript{161} Risk should be differentiated from hazard; however it has been used in common parlance with hazard and danger.

However, if we were to ensure safety based on carrying out product safety assessments alone, is it going to be enough? What about some consumers who are careless or reckless or easily distracted by something, who always find the easy

\textsuperscript{155}Hodges, supra, 2005, chapter 18
\textsuperscript{157}C. Hood, H. Rothstein, ibid.
\textsuperscript{158}Hodges, op.cit., 2005, p. 1.
\textsuperscript{159}G. Howells, op.cit., 2005, p. 1.
\textsuperscript{160}Ibid., p. 22.
\textsuperscript{161}G. Howells, op.cit., 2005, p. 2.
alternative, or who do not pay attention to warnings or instructions for example? It must be remembered that consumers can also be involved in contributory negligence if accidents ever happens. Joerges is of the opinion that safety assessment procedures should be flexible, due to the fact that the danger and risks to be assessed vary greatly in nature and intensity. He therefore concluded that risk and measurement of risk is not supposed to be done by measuring the product and its involvement in accidents alone, but also must include conclusions as to causes and responsibilities.

2.3.2.3. The importance of channelling responsibility for safety of products to the manufacturer

It has been accepted practice to refer to the producer or manufacturer as the party principally responsible for the safety of products. Although there can be ‘no absolute safety,’ putting the responsibility of safety on the producer or manufacturer of the product is very important. According to Howells, it is an obvious ‘cardinal principle when they manufacture the product.’ Apart from the producer or manufacturer, there are also other parties that assume responsibility for safety, such as the retailer. In the case where retailers present themselves as producers by selling goods under their own brand, or someone attaches the brand name to goods, then there is a tendency to also treat them as the producer. Such a responsibility is seen to be necessary not only because of the impression they create on consumers showing that they are in fact responsible for producing the goods, but also because ‘very often these parties will indeed have had a good deal of influence over the production of the products.’

However, it must be remembered that safety does not only concern when the products are made, it is also important that other intermediary parties in the chain must address safety before it reaches consumers. Suppliers, retailers and distributors should also be involved to assist compliance with the law/regulation.

\[163^Ibid., p. 122.
\[164^See for example the wording in the ISO/IEC Guide 51 on the Guidelines for the Inclusion of Safety Aspects in Standards which says ‘...even at the highest level of safety, a product, process or service can only be relatively safe.’
\[166^Howells, op. cit, p. 13
The question then extends to, if a product is an imported product, then who should be held responsible? For imported products, the person/company importing the products should also be responsible for the safety of their imported products because they are responsible for the introduction of such products into the country. They should check first if the products they import are safe for use, or if there are any safety related issues in the products prior to their importation.

2.3.2.4. Precautionary principle

With the present rapid increase in the number of new products on the market which are produced as a result of new sciences and technological innovation, there are different ways to apply new knowledge and innovations. Although the greater benefit goes to the consumer who can enjoy a variety of choices, this development also brings more responsibility and challenges. Therefore, taking additional care in exercising this development is not an option. The precautionary principle is an underlying rationale that is important for many new products on the market. This principle refers to a situation ‘when an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.’

Although still controversial, this principle has now become the guiding principle used to protect humans and the environment against uncertain risks. Whilst the concept of precaution is not a new one, understanding of the precautionary principle has, with time, come to mean different things to different people - for example, Adler claimed that it can inspire ‘fear and trepidation’ in product manufacturers.

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167Wingspread Statement on the Precautionary Principle, January 1998, Science and Environmental Health Network, the Johnson Foundation, the W. Alton Jones Foundation, the C.S. Fund and the Lowell Center for Sustainable Production at the University of Massachusetts-Lowell.

168For example it has been argued by some commentators that precautionary principle does not provide a robust or reliable foundation for regulation, because there are a number of different versions without consensus on what it actually means. See Faunce, Murray, Nasu and Bowman, ‘Sunscreen Safety: The Precautionary Principle, the Australian Therapeutic Good Administration and Nanoparticles in Sunscreens,’ Nanoethics, 2, 2008, p. 232.


170Ibid., p.173.
Born of environmental considerations,\textsuperscript{171} the precautionary principle has since been deployed into many new scientific analyses. It was featured in the EU policy prior to its formal introduction as a legally binding policy in EU environmental law.\textsuperscript{172} The precautionary principle provides a rational approach to the management of uncertain risks to public health, society and the environment. Its aim is to use the best of the ‘\textit{system’s science}’\textsuperscript{173} of complex processes to make wiser decisions. However, it is argued that this principle is intended only to supplement, but not necessarily replace, other management strategies that fall short of being able to handle large-scale scientific ignorance such as ‘when human activities may lead to morally acceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.’\textsuperscript{174} In 2000, the European Commission has published a report on the precautionary principle.\textsuperscript{175} It held that to invoke such a principle it requires reliable scientific data and logical reasoning, leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard’s impact on the environment, or health of a given population including the extent of possible damage, persistency, reversibility and delayed effect.\textsuperscript{176} However it is not possible in all cases to complete a comprehensive assessment of risk, but the principle requires all effort should be made to evaluate the available scientific information.

It can be argued that a more precautionary approach to preventing potential risk of an improper nature may slow down innovation or obstruct scientific progress. This is because new technologies usually introduce new risks. The report also stated that there are huge challenges in understanding developing systems while trying to meet human needs with lower health costs and less ecological damage.\textsuperscript{177}

\begin{footnotesize}
\begin{itemize}
\item The precautionary principle has its beginning in the German principle or \textit{Vorsorge}, or foresight. The principle was introduced in 1984 at the First International Conference on Protection of the North Sea. Following this conference, the principle was integrated into numerous international conventions and agreements, including the Bergen declaration on sustainable development, the Maastricht Treaty on the European Union, the Barcelona Convention, and the Global Climate Change Convention. See further Tickner, Joel, and Raffensperger, Carolyn, \textit{The Precautionary Principle in Action: A Handbook}, Science and Environmental Health Network., p. 2. See also World Commission on Ethics and Scientific Knowledge and Technology (COMEST) for UNESCO, \textit{The Precautionary Principle}, Paris, March 2005, pp. 9-11.
\item Article 130r (now 174) of the EC Treaty 1992
\item Ibid.
\item See Annex 1 of the COMEST, supra, p. 49.
\item See para 5.1.2 of the Report, p. 14.
\item Ibid.
\end{itemize}
\end{footnotesize}
One example of the absence of precautionary principle was the use of asbestos;\textsuperscript{178} a ‘disaster in slow motion’.\textsuperscript{179} There is also fear that an overly wide acceptance of such a principle may lead to precautionary interference that later on proves unnecessary.\textsuperscript{180} The fine line between the two extremes has to be considered on a case by case basis where product safety depends on the nature of the product itself. It has been maintained\textsuperscript{181} that the precautionary principle is not based on ‘zero risk’ but aims to attain lower acceptable risks or hazards.\textsuperscript{182} With regards to cosmetic products, given the complex nature of the safety risk of cosmetics, this approach seems necessary to identify and prevent such risks. Particularly with the use of emerging technologies in cosmetics, such as nanotechnology, such uncertainty or risk therefore needs to be handled with extra care.

\subsection*{2.4 Part II: Regulatory Techniques in Safety Regulations}

Introduction

In the previous section, there was a discussion of the general aspects of product safety regulation, the inadequacies of the role played by product liability remedies, and there was also a discussion about the characteristics considered important for product safety regulations. This part goes further in discussing and analysing the regulatory techniques that are used in product safety regulation. There are several regulatory techniques used to protect consumers from dangerous products. The most common distinction in product safety regulation is usually between pre-market and post-market controls. Pre-market controls prevent unsafe products reaching


\textsuperscript{179}T K, Joshi, ‘Precautionary Principle and the Need to Ban all Forms of Asbestos Use in India,’ \textit{Indian Journal of Occupational Environmental Medicinal}, Volume 6, No 3, July-September 2002, p. 5

\textsuperscript{180}Referred to ‘false positives.’ \textit{Ibid.}

\textsuperscript{181}\textit{Ibid.}

\textsuperscript{182}\textit{Ibid.}
consumers. They are generally directed at the producer in order to influence the manner in which products are manufactured and marketed.\textsuperscript{183} Post-market controls, on the other hand, are concerned with monitoring products in the market place and ensuring that action can be taken once dangers become apparent. These rules are directed at both producers and distributors, including retailers. The examples of the legislation of different jurisdictions are used to give a clear illustration of how the system works.

2.4.1 Pre-marketing Controls

Pre-market controls are an obvious form of intervention in the market to promote the safety of consumers. Requiring control of the safety of a product prior to placing the product on the market is a key procedure that is fundamental to the safety of many consumer products, including cosmetics. The rationale behind the implementation of pre-marketing control is to ensure that the products either through design, performance, function, or safety are adequately inspected and that the predicted standard of each of the said features is acceptable.\textsuperscript{184} In ensuring that a product is safe for consumption, it is necessary to assess the purpose and nature of the product. Hodges suggests that techniques are sometimes adopted in different ways or to different extents in different products.\textsuperscript{185} The techniques used under pre-marketing controls are explained in this section. They are: product bans, prior approval, certification, product standard, product notification and batch marking connected to post marketing.

2.4.1.1. Ban of products

Some risks may be acceptable; however, some others are obviously unacceptable.\textsuperscript{186} For example, the product itself can be inherently harmful in the first place. In the case of unacceptable risks, there can be no compromise on safety and such dangerous products cannot be simply left on the market and available to consumers. As different products carry different risks, therefore there is a necessity to distinguish which product risks are unavoidable and should be eliminated at all

\textsuperscript{183}G. Howells, \textit{op.cit.}, 1988, p. 11.
\textsuperscript{184}Hodges, \textit{op.cit.}, 2005, p. 87.
\textsuperscript{185}\textit{Ibid}.
\textsuperscript{186}G. Howells, \textit{op.cit.}, 1998, p. 11.
costs, and which are tolerable.\textsuperscript{187} Here, risks can exist for an entire product category or for simply particular products or batches (such as due to contamination or substandard products).

Products whose risks are unavoidable are very dangerous and therefore should be banned from the market. This is the first type of ban, that is, the ban which requires a product to be totally prohibited from the market. It is the strictest mode of intervention and should be used only in severe or emergency cases. Joerges argued that banning orders should only be considered when the manufacturer or importer of products is not prepared to remedy the defects ascertained.\textsuperscript{188} Examples of this type of ban are the ban on a product that can cause consumers to develop cancer in the long term, and the ban of cannabis because of the serious physical and psychological effects associated with its use. However, what is the level of dangerousness needed for a product to be banned? In the USA, the Consumer Product Safety Act 1972 clearly specifies that products giving rise to ‘an unreasonable risk of injury’ could be banned unless some product standard promised appropriate protection.\textsuperscript{189} The ban of asbestos is an example of this type of ban and among the most controversial ban. For example, the supply, importation and use of blue and brown asbestos was totally banned within the UK in 1985, with a general ban on white asbestos following in 1999 (there were slight exceptions for the specialist use of white asbestos, however a total ban came on January 1, 2005). In the USA on July 12, 1989, the Environmental Protection Agency (EPA) issued a rule banning most asbestos-containing products\textsuperscript{190} to reduce the unreasonable risks presented to human health by exposure to asbestos during activities involving the products.

Another category of ban is bans on particular products or batches of products (such as due to contamination or substandard products). The formaldehyde (UF) controversies in 1976 are an example of this. The ‘unreasonable risk’ is the possible carcinogenicity of the UF based on medical studies.

As banning orders are considered a drastic technique and are the strongest form of direct intervention, public authorities prohibit the supply of products that

\textsuperscript{187}For the product with tolerable risk, the risk can be reduced through design requirements-see the later section.
\textsuperscript{188}Joerges, op.cit., 2010, p. 103.
\textsuperscript{189}Section 8.
have a serious harmful effect. It has been argued that, compared to product recalls, banning orders occur relatively infrequently.\textsuperscript{191} This can be attributed to the fact that in some products the defects could be more or less easily removed either by equipping, design measures, or making changes to the product instruction, warning or label.\textsuperscript{192}

Banning dangerous products could help prevent or reduce accidents or injuries that might happen if such products are released onto the market. Banning dangerous products, although it is considered a drastic intervention given so many products come on the market, is one of the important elements under product safety regulations against products that are capable of posing a risk to the safety and health of consumers. The danger of products if not banned is accidents which can lead to injury or even death. Statistics reveal that people are being injured or die as a result of risks related to the use of unsafe products since many of these products are easily purchased in convenience stores.\textsuperscript{193} However, as far as cosmetic products are concerned, banning orders are not suitable. Although it has been suggested by Kay\textsuperscript{194} that recent scholarship on cosmetics has largely ignored the effects of accidents arising out of cosmetics, that it can be argued that injuries from cosmetics can be a serious problem if they are not adequately addressed, and equally that there may be long term problems, however, there are very few such products that have caused devastating effects. However, since cosmetics are composed mostly of chemical substances, a ban of certain dangerous substances to be used in the cosmetics composition might be necessary to help prevent any adverse effects coming in cosmetics.

\subsection{Prior Approval}

Apart from banning dangerous products, another strong form of intervention is the control of the supply of products by requiring the producers to obtain a licence before marketing them. Prior approval refers to where an individual or firm is obliged to seek a licence or permit from a regulatory body in order to undertake an

\begin{itemize}
  \item \textsuperscript{191}Ibid.
  \item \textsuperscript{192}Ibid.
  \item \textsuperscript{193}See for example, Hodges \textit{et al.}, 1998, analyses the number of accidents and death from the use of consumer products in the UK. See Hodges, \textit{et al.}, \textit{Product Safety}, Sweet and Maxwell, 1996, London.
  \item \textsuperscript{194}G.Kay, \textit{supra}, 2005, p. 2.
\end{itemize}
activity.\footnote{Ogus, supra., 2004, p. 214.} This type of intervention generally concerns the requirement to have a particular product approved before it can be placed on the market. Generally the approval is given by issuing the licence before the regulated activity takes place. It must be noted that this burdensome requirement can only be justified where there are strong grounds to believe that products may pose unacceptable risks.

This type of control could be used not only to preserve minimum standards of quality but also to limit competition.\footnote{Ibid.} However, it tends to be restricted only to some sectors and does not normally apply to general consumer products. Obvious examples of products categorised under this type of control are pharmaceutical products. According to Ogus,\footnote{Ibid., pp. 235-238.} the restrictions placed on such products are necessary as such products can pose extreme risks. In the EU, there are multinational enterprises and international drug manufacturers and the regulation of pharmaceuticals has assumed considerable importance.\footnote{L. Kramer, \textit{EEC Consumer Law}, 1968, pp. 206-213.} In determining the eligibility for the product licence, the authorities must take into consideration the safety, efficacy and quality of the drug.\footnote{Section 19(1) of the Medicines Act 1968.} The second justification for the relevance of this regulatory technique is the difficulty in obtaining sufficient information about a product.\footnote{Ogus, supra., 2004, pp. 233-235.} Although it seems that prior approval through licensing a product could help prevent a potentially dangerous product from reaching the market, it is suggested that there are risks attached to its use as a regulatory tool.\footnote{Ibid.}

One of the perceived risks relates to the increased costs that result from having the product approved, which may also discourage appropriate research and development.\footnote{Cartwright, supra., 2000, p. 698.} For example, products such as drugs and medicine are particularly relevant for the government intervention as their research and development costs are very high due to the time taken for the research and development which can cause significant delays before the medicine can be marketed.\footnote{Parish, ‘Consumer Protection and Ideology of Consumer Protectionists’ in Duggan and Durvall (eds.), \textit{Consumer Protection Law and Theory}, 1980, The Law Book Company.} Cartwright suggests that such delays ‘may lead to the loss of life of individuals who might have been
saved if the drug had been available earlier.\textsuperscript{204} However, an overly strict system of prior approval could also result in the companies becoming disinterested in investing further in research and development. Ultimately, there is the possibility that this might lessen the number of approved drugs on the market. Therefore this has to be balanced with the risk that greater harm might result if there is no proper system of prior approval in place.

For cosmetic products, prior approval was previously used in certain countries, such as Japan and Malaysia. Application for product registration was made by the product manufacturer to the regulatory authority and the authority had to conduct safety testing before approving the product and before the product could be released on the market. This was considered burdensome and as a result, in 2001, Japan ‘deregulated’ its system while, from 2008, Malaysia shifted to product notification. This means that for both countries, prior approval for cosmetics is no longer applicable.\textsuperscript{205}

In conclusion, it is submitted that prior approval is frequently seen as having a strong preventative role in product safety regulation. Such strict intervention apparently could be extremely burdensome and the requirement can only be justified where there are strong grounds to believe that products may pose unacceptable risks. This is why such a regime tends to be restricted to sectors such as drugs and pharmaceuticals, and does not normally apply to general consumer products, including cosmetic products. (See part III of this chapter for further discussions on this).

\textbf{2.4.1.3. Product certification}

It was explained that sometimes using prior approval could be onerous for the manufacturer/producer. Therefore, the law provides another alternative to tackle such a problem, that is certification or disclosure requirements; less serious modes of intervention. Product certification is the process of certifying that a certain product has passed the necessary performance and quality assurance tests, or the qualification requirements stipulated in regulations, or that it complies with a set of regulations governing quality and minimum performance requirements. According

\textsuperscript{204}Cartwright, \textit{op.cit.}, p. 697.
\textsuperscript{205}Further discussion on Malaysian system is in Chapter 5 and the analysis of the shift from prior approval to product notification is discussed in Part II of the comparative chapter.
to Ogus, product certification is a type of information regulation which not only requires disclosure of product characteristics, but must also indicate that the product complies with a set of standards.\textsuperscript{206} A certification system may closely resemble licensing in the conditions it imposes on applicants with lesser regulatory intervention. It would constitute an indicator of quality to those consumers who wish to make use of it and offers freedom of choice between the certified and uncertified products.\textsuperscript{207} Examples of products which are under the certification system are electrical appliances and safety equipments products. There are certification bodies\textsuperscript{208} that exist to provide certification for such products. A product must meet the criteria provided by the certification bodies before they can be certified. Cosmetics are not suitable for a certification system because these products normally come with a high degree of technical details in terms of chemical substances and safety evaluation.

\textbf{2.4.1.4. Product Standards}

From the previous section, it is understood that prior approval requires a high degree of intervention. However, apart from certification, there is also another form that involves less intervention – product standards.\textsuperscript{209} The standard technique allows the activity to take place without any \textit{ex ante} control. Ogus identifies three types of standard, which are distinguished by their differing degrees of intervention. First is the performance standard.\textsuperscript{210} This standard specifies the quality conditions that must be met by particular products at the point of supply. However, it is left to the supplier or producer to decide how to choose and meet the specified conditions. The second type of standard is the specification standard, which is also known as the design or input standard. This type of standard is set by compelling the supplier or producer to employ certain materials or methods, or by prohibiting the use of certain materials or methods. The example given for this type of standard is motor vehicle. The third type according to Ogus is the target standard, which does not specify any specific

\textsuperscript{206}Ogus, \textit{supra}, p.190
\textsuperscript{207}Ibid., p. 215.
\textsuperscript{208} An example of a certification body is the European Committee for Standardisation (CEN). In the EU for example, consumer products that are under this system are governed by the New Approach Product Directives.
\textsuperscript{209}Howells, \textit{supra}, 1998, p. 27. According to Howells, product standards are usually documents written in a way that is comprehensible to the technicians who have to use them, which sometimes include technical documents.
\textsuperscript{210}This is also known as output standards, see Ogus, \textit{supra}, pp. 150-158
standard for the supplier's processes or output. However, liability is imposed in cases where harmful consequences arise from the output. This has the strength of giving firms a considerable amount of discretion in relation to how they prevent the harmful occurrences. According to Hodges, cosmetics are an example of the products that fall under this category of standards. The regulation of cosmetic products is usually based on the premise that they must not cause harm to human health when applied under reasonably foreseeable conditions of use constitutes ‘a target’ that it imposes liability for certain harmful consequences out of the products.

The advantages and disadvantages of types of products standards

It would seem that each standard has its own advantages and disadvantages. It is sometimes difficult to draw a line between performance and design standards. This is because some performance standards may be so specific that, in practice, the choice of design is severely limited. Equally design standards may still be appropriate where a particular design solution is known to be superior to alternatives or where potential risks are so severe that the producers’ discretion should be curtailed. However, it is claimed that there is a clear trend towards favouring product standards framed in terms of performance objectives rather than design specifications. Howells has suggested that the total prohibition of the use of design specifications in regulations in the USA seems to have gone too far even though there is an understandable desire to allow manufacturers more scope in the creation of new products, thereby increasing consumer choice while remaining consistent with consumer safety.

It would seem that the most important variables in exercising the choice of standards are the costs of being informed of the technological means of achieving the regulatory goals and the administrative costs of formulating the appropriate standards and monitoring compliance. Performance standards are beneficial in terms of allowing producers significant flexibility in achieving their safety goals, and, ultimately, this flexibility increases the tendency to produce an effective method in

\[211\text{Hodges, supra, 2005, chapter 6}\]
\[212\text{Howells, supra, 2005, p. 41.}\]
\[213\text{Ibid.}\]
\[214\text{Ibid.}\]
\[215\text{Ogus, supra, 2004, p. 166.}\]
manufacturing processes and materials.\textsuperscript{216} In short, by specifying the result that must be achieved, rather than what process needs to be followed, the objective is relatively easier to achieve from the producer’s perspective.\textsuperscript{217}

One of the disadvantages of performance standards is that sometimes they are so specific that in practice the choice of design is severely limited. Performance standards, which normally are through the form of maximum emission limits, constitute the most widely used pollution control mechanism.\textsuperscript{218} The design specification standard, however, has an advantage over the performance standard in terms of administration costs. This is because it is relatively easy for the standard enforcer to monitor compliance costs to determine whether or not it has been breached, as they do not differ from one firm to another.\textsuperscript{219} The high degree of certainty of such standards can be attractive to firms in reducing their compliance costs. In addition, there is the possibility that a particular design is superior to others.

There are also disadvantages of specification standards, i.e. they restrain innovation by preventing firms from finding new and more efficient methods of achieving a regulatory goal. Since they have a tendency to induce technological rigidity, they could become outmoded very rapidly due to the advances in technology. Ultimately this could lead to a delay and, importantly, the end result is the major loss to social welfare.\textsuperscript{220} Certainly cosmetics are not suitable for this standard type, especially with many large cosmetics producers expanding their R&D and starting to offer new technologies\textsuperscript{221} in product formulations for more efficient products.

\textbf{2.4.1.5. Product notification}

Product notification is another form of limited regulatory intervention. This is because the notification system does not reach the stage of needing to be approved and need a license for producing products, it only serves to help the regulator or

\textsuperscript{216}\textit{Ibid.}
\textsuperscript{217}However, Howells suggests post-market supervision of the design choices of producers is required. See further Howells, \textit{op.cit.}, 2005, p. 42.
\textsuperscript{218}Ogus, \textit{op.cit.}, p. 167
\textsuperscript{219}Ogus, ibid., and Cartwright, \textit{supra}, p. 699.
\textsuperscript{220}Ogus, \textit{ibid.}, p. 168.
\textsuperscript{221}Among some latest technologies is the ‘infusion technology’ used by some cosmetic manufacturers in their hair products. See http://buy.cosmeticsnow.co.uk/items/keratin?keyword_id=1008359&ad_id=19120527351&ad_pos=101 (last visited 17 June 2012)
relevant authority to monitor the products together with the producers. It also helps to detect any reports of adverse effects on products, especially in the post marketing system. In other words, product notification is intended to be an easy way to administer the system. However the burden of safety is still on the shoulders of the producers/manufacturers. It is also more efficient because this system does not usually take as long as the registration system under prior approval. The procedures of notification do not usually involve high costs for companies, and consequently cheaper prices are charged to consumers. Many consumer products are now subject to this system. Some jurisdictions have introduced this system on cosmetics. The company or person responsible for placing the cosmetic product on the market notifies the regulatory authority responsible for cosmetics where the product will be marketed and the place of manufacture or of initial importation before the product is placed on the market. The product can only be marketed after notification has been sent to the regulatory authority and acknowledgement has been received. The disadvantage of this system is that it does not guarantee the safety of products; it is just a way of administering and monitoring the system.

2.4.1.6. **Batch marking connected to post marketing**

Batch marking is another measure to enable the producers to be informed of risks. It may happen that not all individual products present the risk in question, but only some of the items placed on the market. The hazard may also relate in particular to only some of the products of a certain batch due to product contamination or substandard products. In such cases, consideration should be given to the probability of such a hazard being present in a certain product or stage of production. Therefore batch marking helps identify the products and producers easily. Indeed, products or batch marking can facilitate the effective product recall of a specific identifiable batch, thereby avoiding recalling items unnecessarily. Batch marking is a good practice in the production of cosmetics. It enables the manufacturer or supplier to identify the batch in which the product was manufactured and it is a relatively precise way of enabling traceability. In other words, if a problem should arise, this will limit the quantities of the products which have to be recalled or 'held' in stock pending further investigation.

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222 Such as in ASEAN countries including Malaysia.
223 C. Hodges, *op.cit.*, p. 41.
2.4.2 Post marketing Obligation

Introduction

In the last section, pre-market obligations were discussed. It is understood that pre-market control is one of the regulatory tools used to prevent the market from being flooded with goods that are potentially unsafe. In the case where dangerous goods are already placed on the market\textsuperscript{224} and circulated, there is also a need to have equally effective rules directing the action to be taken when dangerous products slip through the regulatory net. These rules are post-marketing controls. Similar to pre-marketing control, post-marketing controls also have gradually grown in scope and importance worldwide.\textsuperscript{225} Sole reliance on the observance of pre-marketing obligation is generally inadequate. There is a need to supplement the duty to observe the safety requirements by other obligations on manufacturers/producers of consumer products to prevent risks from reaching consumers once they are in the marketplace or to take action even if they are in the hands of final consumers. This rule, therefore, is concerned with monitoring products in the marketplace and ensuring that action can be taken once the dangers are comprehended. They are directed at all links of the supply chain including producers, distributors, and retailers.\textsuperscript{226}

2.4.2.1. Purpose of post-marketing obligation

The essential purpose of this system is to enable the producer to be informed of the risks that might appear when the products are used, to evaluate them and to take appropriate action in relation to the safety of the products already on the market or yet to be produced.\textsuperscript{227} Post-marketing product safety is required for many types of products. However, each product category bears significantly different post-marketing requirements. The nature and extent of the system required varies from

\textsuperscript{224} For example, in the UK, 'placing on the market means' making the product available for the first time, when it is transferred from the manufacturer to be distributed. Further, this applies to each individual product and not to a type of product. Refer further to The General Product Safety Regulation 2005: Guidance for Businesses, Consumers and Enforcement Authorities, August 2005, Department of Trade and Industry.


\textsuperscript{226} For example, according to GPSD 2004 which replaced the 1994 GPSD, the 'Suppliers' in the Regulations may be either 'producers' or 'distributors.'

\textsuperscript{227} Hodges, op.cit., p. 129.
producer to producer and depends on the nature of their activities, and on the characteristics of the product involved. For products such as cosmetics, even though such products do not require pre-market approval (as explained in the previous section), in most jurisdictions, a post-marketing monitoring and surveillance system is still required by the law to guarantee that a product is safe for human use.

In this regard, even though cosmetic products have rarely been associated with serious health hazards, it does not mean that cosmetics are safe to use per se. Particular attention is required to their long-term safety aspects, as cosmetic products may be used extensively over a large part of the human lifespan. Consequently, the post-marketing obligation for cosmetic products is also important as it will enable the producer to be informed of the risks that appear from the use of the cosmetic, as well as to take appropriate action when there is any possibility of danger resulting from such use in the long term. It is also important to note that often post-marketing action needs to be invoked with urgency as problems suddenly reveal themselves.\textsuperscript{228} Howells proposed that the law seems to recognise the difficulty enforcement authorities face when having to react at speed to developing situations in which there is uncertainty about the extent and real nature of danger, if any, posed by the product.\textsuperscript{229} Here, consumer safety is given priority, thus, the right of consultation and appeal are typically postponed until the emergency measures have come into effect.

\subsection*{2.4.2.2. Criteria Considered for Post-marketing Obligation}

Before analysing the tools used in post-marketing control, it is also important to discuss the theoretical evaluation of post-marketing controls. Micklitz\textsuperscript{230} and Hodges\textsuperscript{231} have analysed the obligations in which measures are suggested to ensure the efficiency of the post-market control. This is called product monitoring duties. One of the ways is that the information system and technical documents are required to be kept properly and made available. Such documents should include a product’s design and labelling as well as a risk assessment. According to Joerges, ‘follow-up’

\textsuperscript{228}Howells, 2005, \textit{op.cit.}, p. 50.
\textsuperscript{230}Micklitz and Roethe, \textit{op.cit.}, 1994.
\textsuperscript{231}Hodges, \textit{op.cit.}, chapter 11.
control is necessary in regulating the safety of consumer products after the products with the unavoidable risks are eliminated and for some products their risks are reduced through design requirements.

Hodges considered that there is also the need to collect and record the safety information from users, retailers, distributors, regulators, or any other sources, including scientific and technical literature on how safe the product is in practice and whether it continues to conform to the standards of safety as these evolve in the light of new scientific and technical information. Apart from that, the assessment or evaluation of that information, perhaps with external technical, regulatory, medical, or legal advice, and updating the product’s risk assessment is thought to be one of the most important aspects of the post-marketing system.

The system should also include information requirement to a regulatory authority. There are two main purposes in imposing this requirement. One is the situation in which the assessment of safety issues is deemed to be of sufficient importance that it be undertaken by a public authority independently of the manufacturer, which usually involves expert scientific or technical input. The second reason is that the imposition of a reporting requirement is an incentive for producers to observe all their pre and post-marketing obligations. It also provides an opportunity for authorities to check post facto that they have in fact done so. According to Hodges, both these aspects have theoretical justification as regulatory cures for market operators anticipated failures. Lastly the implementation of the decisions after the assessment is made must involve identification of all hazards, and assessment risks associated with each hazard within the scope of the foreseeable use of a product before taking appropriate action.

In the case of cosmetics, authorities play an extensive role, as part of the post-marketing obligation. Cosmetic safety is an example of where producers and manufacturers have an obligation to keep available data such as information systems and technical documents, including the data on undesirable effects on human health resulting from the use of the cosmetic products. This enables better control and more effective monitoring.

Withdrawal and recall

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232 Joeges, op.cit., p.118
233 This has been discussed in part II.
234 Such as in medicinal products and medical devices.
As explained, post-market controls are measures directed at traders who have potentially dangerous goods that they intend to market or they have already marketed. Some of the most serious risks to consumers arise from dangerous products that have already found their way into the possession of consumers. Product recalls are probably the most controversial tools being discussed. Pruitt and Peterson\textsuperscript{236} describe a typical product recall as ‘when the items in question are determined to represent significant substandard product quality or to be unusually hazardous.’\textsuperscript{237} In order to justify whether recall is feasible it depends on the ability to trace product and purchaser. Such ability varies greatly according to the type of products involved. Weatherill and Woodroffe\textsuperscript{238} suggest that recalls are likely to involve large, expensive goods, where chain of supply between manufacturer and consumer is short\textsuperscript{239} or at least well documented. For cosmetics, although they are not usually large and expensive products, recall is good practice. Cosmetics products which have batch numbers are easy to trace thus making recall feasible for such products. This allows the manufacturers to determine which batches need to be traced since sometimes the defective can be pinpointed fairly accurately. In cases where no badge numbers are attached to products, it is suggested that the manufacturers should keep a record of distributors of their products so that they can be traced.

In ensuring the success of recalls, it is also suggested that there are important elements to be considered, for example whether the product manufacturer or retailer have the lists of consumers available, and in some cases it is also necessary that the media are used. In light of this, for example, the recall of motor vehicles where normally purchasers go through agencies, makes it easier to trace the products, should there be any fault. However, less specialised goods are thought to be more difficult to recall. Such products may have passed through more than one distributor and retailer after leaving the manufacturer and before reaching the consumer; therefore, their actual ownership is seen to be more difficult to trace because of no


\textsuperscript{237}Ibid., p. 114


\textsuperscript{239}Short here means the chain involves few intermediate suppliers.
record of sale. Both recall and withdrawal both are the tools used once the products have or are believed to cause hazard to consumers.

It is noted that, even though recall should only be used as the ‘last resort’, it is still the most effective instrument and a useful tool that could be used even to solve general product safety problems, including for cosmetics. It is also an appropriate way of communicating precise information about the danger of products to the public in a timely manner. To allow dangerous products to remain on the market or reach the consumer could constitute a health hazard to them while implementing a recall might mitigate losses. Also, it has significant advantages for the cosmetics authority as it relieves them of the burden of multiple seizures where there is in fact a hazard. As for consumers, it expedites recovery and removal from use of such products which eventually will protect them from the dangerous effects of the cosmetic.

However, there is a significant difference between recalls and withdrawal. Withdrawal means to permanently prevent a person from further supplying a product that is believed to be dangerous where it is already on the market (if the voluntary action taken by producers and distributors is insufficient or unsatisfactory) or from placing it on the market if it has not yet been so placed. This involves situations where goods still in supply chain and have not reached final consumer. Whereas the recall of products is where an enforcement authority has reasonable grounds for believing that a dangerous product has already been made available to consumers and voluntary action falls short of that considered necessary and sufficient to remove the risk. This power, as mentioned, however, is only used as no other measure available to the authority will suffice. In the EU for example, the EC's General Product Safety Directive requires authorities to have the power to recall dangerous products. Under the Directive, recall obligation refers to any measures aimed at achieving the return of dangerous products that have already been supplied or made available to consumers by the producer or distributor.

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240 See page 43 of this thesis, in Chapter 2.
244 In the latest version that is 2005.
245 Article 2(g) of the EU Directive.
In the previous Directive, there were some issues regarding whether withdrawal included the return of goods which were already in the possession of the final consumers. The revised Directive fundamentally clarified the requirement of businesses to respond to product safety concerns so that businesses now have the duty to recall dangerous products which have left the stores and are in the hands of the final consumers.

This reform has ushered in compulsory recalls in the EU in case the previously voluntary recall is not conducted by the manufacturer. It has also brought the European community into line with the position in the United States, which has long relied on business notification and recalls as important regulatory tools exercised by the US Consumer Product Safety Commission (CPSC). In fact, the USA has been the forerunner in introducing recalls (since 1972), and has been considered a success due to the impressive figures reported. For example, although just started in 1972, from 1973-1980, it was reported that there were 2500 recall actions, with 100 million products successfully returned.

According to Statler, recalls are the most effective instruments that can be used even to solve general product safety problems. Howells and Fairgrieve viewed the introduction of such provisions in the EU/UK as representing another fundamental shift in the way the law impacts on product safety risk-management, and dubbed it as one of the examples of the ‘Americanization’ of product safety.’ Nevertheless, the introduction of such recall in the EU was ‘the most controversial’ aspects of the transposition process, as some critics felt that enforcement authorities might lack experience in recall and that there could be over or misuse of the power.

246 The United States Consumer Product Safety Commission (CPSC) is an independent agency of the United States government created in 1972 through the Consumer Product Safety Act to protect against unreasonable risks of injuries associated with consumer products.
247 The CPSC has long used recall as a major weapon in promoting safety, and has developed a sophisticated scheme for gradating the response to the degree of hazard. See Howells at note 27 of Regulation of Product Safety, 2005; Fairgrieve and Howells, p. 65.
249 Statler, supra, p. 79.
Also it could be argued that the industry might no longer take responsibility itself if government has the powers. The new obligation reaches further than the previous requirement to withdraw products from the market and increases the burden of the producers and the distributors to monitor products in the distribution chain including those already in use by consumers. It is further supported by the increased power of national enforcement authorities to order or coordinate, or, if appropriate, to organise together with (or require of) the producers and distributors’ recalls from consumers of any dangerous product and their destruction.\textsuperscript{252} Despite the fact that recall should only be used as ‘the last resort,’\textsuperscript{253} it also highlights the importance of authorities organising and ordering the recall and destruction of products if the action of the producers and distributors in the fulfilment of their obligation is unsatisfactory or insufficient.\textsuperscript{254} Although the CPSC has power to mandatory recall of many consumer products, in the USA, as far as cosmetic products are concerned they are outside the scope of this power, as recalls\textsuperscript{255} of cosmetics are voluntary actions taken by manufacturers or distributors to remove from the market place products that represent a hazard or gross deception.\textsuperscript{256}

In short, although it can be argued that recalls of product cannot eliminate the hazard fully (as not all products are returned after recalls), it is still incredibly important because it helps to protect consumers when the dangers are understood and without them, the safety of consumers would be affected.

\textbf{2.4.2.3. Enforcement and punishment over product safety}

In monitoring and surveillance, whichever authority is given the task of enforcing consumer safety, it is imperative that they have adequate powers to track down and act against dangerous goods. This requires them to have access to all levels of the production and distribution chain. They should have the power to take and test samples and to require the production of relevant documents. It is also important that they have the right to act against suspect as well as obviously dangerous products. Cartwright\textsuperscript{257} has considered certain internal\textsuperscript{258} and external\textsuperscript{259} elements

\textsuperscript{252}Article 8 (1).
\textsuperscript{253}Article 8(2).
\textsuperscript{254}Article 8 (2).
\textsuperscript{255}Recalls are addressed in Title 21 of the Code of Federal Regulations (CFR), sections 7.40 and 7.59.
\textsuperscript{256}See detailed discussions in the USA chapter (Ch. 4) and the comparative chapter(Ch. 6)
of enforcement. Regarding the external elements, he asserts that enforcement authorities are likely to be influenced by public perception of them and their actions,\textsuperscript{260} which in many cases, according to him, will provide an incentive for the enforcement authorities to take formal action.

It is important that the authorities should have information about risks present within their territory, so that they can take action themselves and also to ensure that information can be passed on to other countries. The USA has an interesting technique for obtaining such information which it does by placing the responsibility on producers and traders to notify Consumer Product Safety Commission (CPSC) of risks. Howells\textsuperscript{261} considers this approach useful, particularly in times of reduced resources, although it should be stressed that market surveillance by enforcement officials should not be done away with altogether. If self-reporting is to be relied upon there must be effective sanctions to ensure that traders take their reporting obligations seriously.

The enforcement authority also needs powers to seize and detain suspect goods. This is because dishonest traders may try to sell the goods to innocent traders or consumers or they could pass into the hands of traders who do not appreciate dangers. Often this power will be available where goods are merely suspected of breaching safety rules, and it is in these situations that the rules exposing authorities to compensation claims usually have their greatest impact.\textsuperscript{262} Dangerous goods should usually be seized and destroyed to ensure that they do not find their way back into the distribution chain. In some cases, it may be possible for goods to be rendered safe by modifying the goods. However, it must be noted that not all goods are suitable to be modified. Cosmetic products and other personal care items for example, are not suitable to be modified and sold back to the consumers due to the nature of such

\textsuperscript{258}Proportionality, voluntary action and risk-based regulation, the precautionary principle and compensation as the internal elements of the exercise of enforcement, \textit{op.cit.}

\textsuperscript{259}Public perception, resources and prosecution and perception of culpability are the external elements of enforcement according to Cartwright. \textit{Ibid}, 2006.

\textsuperscript{260}Cartwright,\textit{op.cit.}, p. 538.

\textsuperscript{261}Howells, \textit{op.cit.}, p. 49.

\textsuperscript{262}\textit{Ibid.}
products. The next part will discuss the approach that is considered appropriate for regulating the safety of cosmetic products.

2.5 Part III: Selecting the Right Approach for Regulating Safety for Cosmetics

Introduction

In deciding the best approach to regulation, it is a question of identifying the important characteristics of a ‘good’ or ‘sensible’ system. Such a system involves two areas. The first relates to the instruments or legal forms selected to achieve the desired aims and objectives. These should be appropriate in the light of economic and social justifications for government intervention and their predicted impact on the regulated jurisdiction. The second relates to the procedure or process by which the instruments are formulated and applied. The development of a new cosmetic or personal care product involves numerous scientific disciplines and multiple areas of expertise, including chemistry and biochemistry, engineering, formulation science, packaging and quality assurance etc. Extensive testing is undertaken to ensure safety and quality is conducted throughout the product development cycle. The process of determining the safety of a cosmetic or personal care product is complex and multi-tiered and requires constant and ongoing assessment of the latest toxicological and medical literature and safety evaluation techniques.

Since every cosmetic and personal care product is a combination of many chemical ingredients, careful selection of safe and well-researched ingredients is a primary consideration in ensuring the safety of finished cosmetic and personal care products. The first step in the evaluation of the safety of a finished cosmetic product is to review the complete safety information on all of the ingredients it contains. This part examines the techniques in the determining the safety of cosmetic by taking the general characteristics of the safety regulations previously discussed in Part 1. It should be noted that the analysis in this part is based on the type of products cosmetics generally are and the most ideal techniques used for cosmetic safety. The implementation of the techniques/approaches of several jurisdictions give some clear illustrations of the techniques deployed and are also mentioned but the specific
implementation of the selected jurisdictions will be examined in detail in the next three chapters.\textsuperscript{263}

\subsection*{2.5.1 The right approach for ensuring regulation of cosmetics safety; public regulation vs. self-regulation}

The cosmetics industry promises\textsuperscript{264} that their innovation will provide new and safe products for the millions of people who use them every day, throughout their lives. It must be remembered that consumer safety should be the principal objective for the manufacture and sale of cosmetics by the cosmetics industry. The most important responsibility for product safety lies with manufacturers. To meet the obligations for safety under the law, the manufacturer needs to fulfil specific duties before placing a product on the market which include safety assessment, provision of product information and compliance with ingredient and labelling rules.

All the earlier mentioned procedures are typically the elements under public regulation for cosmetics which are practised in most jurisdictions in the world. In some jurisdictions, however, cosmetics are governed by self-regulation.\textsuperscript{265} There is a rationale behind the self-regulatory scheme for cosmetics. It should be reiterated that, consumer products now, including cosmetics, embody a wide range of different products which cause a number of problems for the regulators. Here, since product regulators have to deal with numerous products, each product sector requires its own technical knowledge and expertise especially because it has its particular design and is always subject to new innovation and invention. Such knowledge is typically held by the product manufacturers/producers who are not only expert, but also able to utilise that expertise for better and supposedly safer results.

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{263}Chapter 3, 4 and 5 respectively for the discussions on the cosmetic safety schemes of the EU, the USA and Malaysia.
\item \textsuperscript{265}Example: the USA. According to Ogus, self-regulation is law formulated by private agencies to govern professional and trading activities. See Ogus, ‘Self-Regulation,’ University of Manchester, 1999, p. 1. Also mentioned in Ogus, ‘Rethinking Self-Regulation,’ \textit{Oxford Journal of Legal Studies}, Volume 15, 1995, pp. 97-108. Self-regulation has also been referred to as 'modern corporatism,' the acquisition of power by groups which are not accountable to the body politics through the conventional channels. See Schmitter, Phillippe C., ‘Neo-corporatism and the State,’ in Grant, Wyn (ed.), \textit{The Political Economy of Corporatism}, 1985, London, Macmillan, pp. 32-62.
\end{enumerate}
\end{footnotesize}
Self-regulation is considered a common arrangement in developed jurisdictions, and Heeks and Duncombe believe that it is particularly suited to a rapidly liberalising international trade environment. The USA, for example, has been known to have a self-regulatory system for cosmetics. Self-regulation normally involves the system of private ordering (normally by specified agencies or industries) without any form of intervention or with only minimal intervention by the regulators. Ogus specifies the advantages of self-regulation by agencies/industries; first, they have greater expertise and knowledge of technical practices within their relevant area than the regulators do. It is of course the cosmetics industry itself that is expert in its own field. Second, it is less formalised than public regulation so it costs less to administer (this includes the costs associated with delays). With regards to cosmetics, it involves fewer formalities because there are no onerous procedures – such as approval or product registration. Lastly, the costs of administration are internalised in the activities which are subject to regulation.

There are however many longstanding criticisms of self-regulation. For example, Shaked and Sutton have stressed that such rules may create barriers to entry while Tullock called it ‘a social deadweight loss.’ Although such arguments against self-regulation are only appropriate in ‘some circumstances as they are based on an incomplete picture of the self-regulation,’ in some parts they are true. Cane suggested that it can lead to potential abuse which might affect third parties. Although data is lacking in order to prove such a claim in relation to the cosmetics safety scheme, self-regulation of cosmetics might be challenged in terms of producing products that might not be safe enough or of good enough quality. If that is the case then the safety of consumers might be at stake, and this is unacceptable. Although the industry or agency has standardised procedures to ensure that this will not affect the consumer, it is thought that regulating cosmetics safety might be better under public

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268 Ibid., p. 1.
270 Ibid.
regulation.\textsuperscript{274} In addition, as explained earlier, since the industry/agency is the expert in its own field, as in the case of the cosmetics industry, it is very beneficial to have co-regulation between the regulatory authority and the industry in order to ensure better protection for consumers by providing them safer cosmetics.

\textbf{2.5.2 The current regulatory model for cosmetics}

Previous discussions have been on the type of regulation used in cosmetics safety, this section analyses the existing regulatory model for cosmetics. In a report by Risk and Analyst Limited for the European Commission DG Enterprise,\textsuperscript{275} it is observed that the current regulatory framework for cosmetics in the major markets follows three broad models. The first model consists in a broad definition of cosmetics, with their safety ensured through controls over ingredients in the form of lists of approved, prohibited and restricted ingredients; specific requirements concerning safety testing; and the maintenance of data files on safety. This is broadly the model of regulation in the EU, which is a modern approach applying a vertical, risk-based directive.\textsuperscript{276} In recent years it has become an international model, which is easy to understand and relatively easy to apply.\textsuperscript{277}

The second model contains a narrow definition of cosmetics, with few restrictions on the ingredients that can be used. 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, which is considered by some as the most liberal\textsuperscript{278} one compared to the other two.

The third model is the strictest of the three. It comprises a system known as pre-approval requirements which is based on the administration of regulations that

\textsuperscript{274} Chapter 4 (the USA chapter) discusses thoroughly the implementation of self-regulatory system for cosmetics in the USA.

\textsuperscript{275} Risk and Analyst Limited for the EC DG Enterprise, 'Comparative Study on the Cosmetic Legislation in the EU and other Principal markets with special Attention to so-called Borderline Products,' August 2004.

\textsuperscript{276} Ibid, p.17.

\textsuperscript{277} Outside Europe, a number of countries and/or regions have used the EU model in drafting their own cosmetics 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. See the Risk and Analyst Limited, 2004, also see McMillan, Rory and Lisansky, Steve (eds.), \textit{Global Cosmetic Regulatory Harmonization: An Impetus to the Development of Export Markets, Proceedings of an International Cosmetic Industry Congress, 1998}, CPL Press.

\textsuperscript{278} Gagliardi, L and Dorato, S, \textit{op.cit.}, 2007, p.3. Note that the USA’s law that regulates cosmetics is the Federal Food Drug and Cosmetic Act which was regulated since 1938.
restrict even the choice of common ingredients. Japan was an example of this positive list system\(^{279}\) where each ingredient used in cosmetic formulation has to be pre-approved by the Ministry of Health, Labour and Welfare (MHLW) formerly known as the Ministry of Health and Welfare (MHW).\(^{280}\) This third model may not be an efficient system as it could be burdensome to the manufacturer; it could also result in delay in innovation. In the end, the increase in the cost will be borne by the consumers. Therefore, the pre-approval system of cosmetic has been deregulated in Japan since April 2001.\(^{281}\) Apart from Japan, Malaysia also implemented prior approval; the registration system and licensing for cosmetics prior to the introduction of the notification system which has been in place in 2008.\(^{282}\)

More specifically, the system of pre-approval for cosmetic is onerous for the following reasons:\(^{283}\) First, registration delays the launch of cosmetics that change quickly in line with developments in technology and/or fashion. Second, it does not prevent fraud or stop illegal products reaching the market. The third reason is that in any event, pre-market surveillance is needed to monitor the system, implying a duplication of enforcement procedures. Lastly, time-consuming procedures and high-registration costs imply higher cost for companies and consequently more expensive prices borne by consumers.

As explained in Part II, one of the most important elements in ensuring the safety of cosmetics is the safety assessment, which, for cosmetic products, it is a risk-based process.\(^{284}\) As nothing is free from risk,\(^{285}\) Betton for example argues that if material of a low inherent health hazard is used, then the risk is likely to be low.\(^{286}\) For the majority of people, many cosmetics can be used with no adverse effects at all,

\(\text{\scriptsize \begin{enumerate}
\item In Japan, the licensing of cosmetic is through The Comprehensive Licensing Standard or known as CLS.
\item Gagliardi, Dorato, \textit{op.cit.}, p. 39.
\item Effective from 1 April 2001, new regulations, such as Ordinance No. 125/2000 and Notifications Nos. 330/2000, 331/2000 and 332/2000 from MHW and Notification No. 990/2000 from Pharmaceutical and Medical Safety Bureau, partially revising the Pharmaceutical Affairs Law (PAL) changed the cosmetic system in Japan. This so-called ‘deregulation’ implied a drastic change from the past: the abolition of the pre-market approval or licensing system for each cosmetic product, meaning that the manufacturer/seller is now responsible for ensuring that any marketed cosmetic is safe and to substantiate its harmlessness. See Seminar Report of Cosmetic Regulation in the EU and Japan, 8th September 2009, Tokyo, organised by EU-Japan Centre for Industrial Cooperation. See also Gagliardi, L and Dorato, S, \textit{op.cit.}, 2007, p. 4.
\item See further discussions in ch.6, part II.
\item Gagliardi, L and Dorato, S, \textit{op.cit.}, p. 4.
\item \textit{Ibid.}, See ‘Risk Assessment’ section in Part 2 of this chapter.
\item \textit{Ibid.}
\end{enumerate}}\)
and therefore such products have seldom been associated with serious hazards to health.\textsuperscript{287} Amparo \textit{et. al},\textsuperscript{288} have analysed the risk evaluation of cosmetic products. According to them, the evaluation of risk in such products needs to be in accordance with the following five concepts:\textsuperscript{289} review of the cosmetic ingredients, determination of potential toxicology ingredients, evaluation and testing of human health impact, examination of cumulative exposure to the human body, and testing and evaluation performed by scientists trained in product safety. Although the concepts mentioned are typically the elements under public regulation, such as practised in the EU, it is undeniable that such methods are the most ideal components for determining the safety of cosmetic products. Moreover, for the most part, certain general principles of these components are widely accepted, including in those jurisdiction that have self-regulation, such as the USA.

\subsection*{2.5.3 To what extent should cosmetics producers/manufacturers be responsible for cosmetics safety?}

For cosmetics manufacturers, safety should be the guiding principle for producing cosmetics. They should be responsible for verifying the safety of substances before using them in the product composition, and consider how it might be used in all reasonably foreseeable conditions. It is also important to take into consideration the packaging and labelling of products; which should include any warning or instructions for use as well as matters relating to its disposal. The principles of pre-market controls of cosmetics should place the safety obligation on manufacturers, distributors and importers (or any persons responsible for placing the cosmetics products on the market). Compliance with the regulations should be controlled by the national or regional competent authorities. Some countries have established specific practices for the manufacture of cosmetic products, usually named Good Manufacturing Practices (GMPs), in order to avoid possible problems or errors in each and every step of the manufacturing process.\textsuperscript{290}

The responsibilities that they should have are as follows. First, they should have responsibility for ensuring that banned substances are not used in

\begin{thebibliography}{99}
\bibitem{288} Amparo, S (eds.), \textit{supra}, 2007.
\bibitem{290} COLIPA, COLIPA Annual Report of 2003.
\end{thebibliography}
formulations. As each cosmetic product is considered a unique mixture of chemical substances, one of the major aspects to be considered in ensuring the safety of cosmetic products concerns the ingredients used in their composition. It is generally accepted that a safety assessment should be carried out in order to ascertain the toxicity of its ingredients and the chemical properties. This is a key point as the substances provide crucial information for predicting certain toxicological properties. Second, they should be responsible for conducting safety testing. It should be obligatory for the manufacturer/producer to carry out a safety assessment. Further, the person who carries out the safety assessment must have adequate qualifications and relevant experience.

Third, they should be responsible for providing appropriate information to consumers, which should be done through labelling. The label information should include the expiry date as well as a batch number/manufacturing code, and the function of the product (unless it is clear from the presentation). Fourth, they should be responsible for reporting any adverse effects. The reason for this obligation is that it can be a means of early detection if there are any serious problems concerning the product. Although it is noted that undesirable effects as a result of normal and reasonably foreseeable use of cosmetic products are usually mild and rare, they should not be taken lightly by the cosmetics industry. It can also help prevent any serious harm resulting from minor effects especially in long term usage. Finally, they have the responsibility for conducting post marketing activities.

Safety assurance does not end even after a product is placed on the market. Once a product is released to consumers, the producer/manufacturer needs to engage in active monitoring of the product to ensure its continued safety. The rationale of giving this responsibility is for the identification of potential safety issues related to their products. Hodges asserts that although it can be argued that consumers do not normally need to be able to identify all ingredients before buying the product, if they subsequently develop allergies to particular ingredients the information first needs to be available to toxicologists. They will then undertake patch testing to identify the sensitising ingredient and will be familiar with all names

291 B. Fernández de Córdova Manent and E. F. González Abellán, op.cit., p 31
292 Ibid., p. 31
293 See later section
294 For example, in the EU, the expiry date has been prescribed as the date of minimum durability, or period after opening (PAO), Article 6(1) of the EU Cosmetic Directive 76/768/EEC
used and can inform individuals to beware of particular names for specific ingredients.\textsuperscript{295} On the other hand, anyone who has an allergy to an identified substance will need to know its name, in whatever language, and this is an issue for consumers to be aware of new variations or combinations.\textsuperscript{296} In the next chapters, it will be shown which of the jurisdictions compared actually implement these measures.

2.5.4 Importance of information in cosmetic safety regulation

It is undeniable that information plays the key determinant in ensuring that consumers have adequate awareness/knowledge about the safety of cosmetic they use. This is important as information (such as labelling of product, warning and instructions) can be used to avoid the potential danger in cosmetics. Lewis\textsuperscript{297} for example highlighted that the listing of cosmetic ingredient on the packaging is the only place ‘where a consumer can readily find out the truth about the cosmetic products she/he is buying.’\textsuperscript{298} As previously mentioned, information regulation has long been recognised as a central function of safety regulation.\textsuperscript{299} Although it has been argued that warning and instructions are much less effective as preventive measures than design changes,\textsuperscript{300} nevertheless without such information, it is even more difficult for the consumer to predict risk. It is essential that producers must provide consumers with the relevant information to enable them to assess the risks inherent in a product through the normal or reasonably foreseeable period of its use. Producers must also monitor in an appropriate manner the safety of product placed in the market. Furthermore, if necessary, they must take appropriate action, including withdrawing the products from the market, to avoid injuries from happening. For cosmetics, the labelling of cosmetics necessitates the identification of ingredients through a common name as specified in a Common Ingredients Nomenclature, known as INCI. INCI is the official dictionary for cosmetic ingredients; which has been established in the early 1970’s by the Personal Care Products Council (PCPC).\textsuperscript{301} Many countries require manufacturers of cosmetic ingredients to submit

\textsuperscript{295}Hodges, 2005, \textit{supra}, p. 126
\textsuperscript{296}Ibid.
\textsuperscript{297}C. Lewis, ‘Clearing up Consumer Confusion,’ FDA Consumer, August 2000.
\textsuperscript{298}Ibid.
\textsuperscript{299}C. Hodges, 2005, p. 117.
\textsuperscript{300}D. Lucas, \textit{supra}, 1999, pp. 18-19. This has already been mentioned in footnote 56 in the Part 1.
\textsuperscript{301}Formerly known as Cosmetic Toiletry and Fragrance Association or CFTA
all new ingredients for registration in the INCI system. If the cosmetic manufacturers intend to sell their cosmetic products, for legal labelling requirements, they need to use the official INCI name of the ingredients on the label. Cosmetics which fail to bear the required information cannot lawfully be sold in the three jurisdictions covered in this thesis. In short, these laws are particularly intended to protect consumers from health hazards and misleading practices and also to assist them to make informed decisions regarding product purchase.

2.6 Conclusion

In the market where consumer goods are increasing in complexity and sophistication, consumers are unable to anticipate risks and safeguard themselves. This means that there is an urgent need for government intervention in the marketplace for consumers who need protection, although without prior approval scheme. In this chapter, theory on what makes a good safety regime is discussed. Since cosmetics are consumer products which are now receiving better attention than before, the safety of such products is as important as other consumer products. Here, although the manufacturer of a cosmetic product has sole authority and responsibility to decide to market a product, his freedom of action must be circumscribed by certain requirements. One of the examples is the requirement to use only ingredients listed as approved by a relevant scientific panel. It appears that a good safety regime requires a uniform regulatory framework, where safety is the direct responsibility of the manufacturer, and where authorities are in charge of not only through pre-market control but also of post marketing surveillance activities. In addition, standardized labelling and providing full transparency of information to the consumers is essential for the majority of products, including cosmetics in the light of providing better safety standards for consumers.

The next three chapters analyse the cosmetics safety system in the compared jurisdictions to see which of them uses the ideal approach discussed in this chapter. It starts with the EU, the practice and criteria in its cosmetics safety regime followed by the USA’s cosmetics safety mechanism, which is well-known for its self-regulation. Lastly an analysis will be done of the Malaysian implementation of the cosmetics safety regulations which were adapted from the EU Cosmetic Directive.
Chapter 3: Regulation of Cosmetics in the European Union (EU)

3.1 Introduction

The cosmetics industry is a global one in which the EU is one of the biggest players. This is evidenced by the fact that the EU cosmetics market in 2009 was worth €69.5 billion, making up almost a third of the global market.\textsuperscript{302} The output of EU cosmetics companies is approximately twice that of Japan and a third of the USA.\textsuperscript{303} A report by the European Cosmetics Association (COLIPA) in 2009 revealed that, in the EU, there were over 3,000 cosmetics manufacturers\textsuperscript{304} and these created over 500,000 jobs directly and indirectly.\textsuperscript{305} Like other markets, cosmetics in the EU are subject to regulatory controls in order to ensure the safety of products and avoid adverse impact on consumer health.

In the EU, the current regulatory framework is legislated by the EU Cosmetics Directive.\textsuperscript{306} Without implementing prior approval, the Directive ensures the safety of cosmetic through specific methods such as; controls over ingredients and through the requirements on manufacturers concerning safety testing and maintenance of data files, information provision and labelling requirements. A study conducted by Risk & Policy Analysts in 2004\textsuperscript{307} for the European Commission showed that the framework in place had driven innovation and increased the industry’s ability to compete, and furthermore that it compared favourably to other markets. This can be attributed to the fact that the EU regulatory framework in cosmetics safety is considered comprehensive and that safety aspects are treated with the utmost importance.

In the EU, safety assessments are a main element in the systematic approach towards the safety of a cosmetic product.\textsuperscript{308} Another required element is product safety information; containing data on the quantitative and qualitative composition

\textsuperscript{302}COLIPA, COLIPA Annual Activity Report 2009, Brussels, p. 20.
\textsuperscript{304}Ibid, p. 21.
\textsuperscript{305}It is also reported that the majority of the approximately 4,000 EU cosmetics companies are the SMEs. Ibid., p. 21.
\textsuperscript{307}Risk and Policy Analysts was commissioned by the European Commission (DG Enterprise and Industry) to carry out a study on borderline products of the major market of cosmetic in 2004, infra.
\textsuperscript{308}According to Article 2 of the Directive 76/768/EEC, only safe cosmetic products can be produced and marketed in the EU.
of the products, the toxicological profiles of the ingredients, exposure conditions, and undesirable effects. The Product Information File (PIF) was also introduced, which provides a description of the cosmetics being marketed, the method of manufacture, a statement of compliance with good manufacturing practice, proof of claims and any animal testing data which has been conducted. Finally, but no less important, the EU has found that efficient market surveillance is crucial to ensure that the provisions of the Directive are followed. As previously analysed in the theoretical chapter, pre-market obligations, together with the post market surveillance are the important elements in ensuring the safety of cosmetic on the market in the EU.

The original 1976 EU Cosmetics Directive which at the moment still regulates this area consists of 53 amendments and more than 70 technical adaptations that have been added over the past three decades. It contains several guiding annexes for the substances used in cosmetics. Although the EU has now developed the 'New Approach Directive' to streamline product approval for a broad range of goods in order to facilitate trade between the EU internal market, cosmetics are still covered under the 'Old Approach Directives.' This is because cosmetics are specific products that have technical details outlining the minimum requirements a product must meet and the technical details are found in the Directive itself, whereas the 'New Approach Directives' are more general in the sense that the Directives only set out generic essential requirements, while the technical details are instead established by European standardisation bodies such as CEN, and importantly do not form part of the test of the Directives.

Further, adapting to existing and new developments in the cosmetics industry, the EU is considered to be at the forefront of new policies on cosmetics. In the development of the international trade where standardisation of regulation has become of paramount concern, harmonisation has been high on the agenda in the EU.

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309 The EU Cosmetics Directive has been amended by the European Parliament and the Council in order to reflect new trends and safety concerns on cosmetic products.
310 Apart from these so-called 'amendments,' the Commission has adopted many 'adaptations' in order to adapt to technical processes provisions as well as chemical substances in the annexes to the Cosmetics Directive to technical progress.
312 Examples of products covered under the New Approach Directives are machinery products, electrical products and medical devices.
313 CEN is the European Committee for Standardization
Consequently, with different regions of the world moving forward to embrace the global regulatory harmonisation on cosmetics, the EU became the first harmonised region in respect of cosmetics regulation. Considered a success, the harmonisation of cosmetic regulations for EU countries is regarded as the model for other regions. This can be demonstrated by the fact that the South-East Asian (ASEAN),\textsuperscript{314} Mercosur\textsuperscript{315} and the Comunidad Andina(Andean Pact)\textsuperscript{316} have adopted the EU Cosmetics Directive as a model for harmonisation of cosmetic regulations. Apart from that, there are also other countries that have adopted certain elements in the EU model, such as: India, Morocco, China, Algeria, Israel, Saudi Arabia and some other countries.\textsuperscript{317}

On 30 November 2009, the new Cosmetic Regulation\textsuperscript{318} was adopted, replacing the EU Cosmetics Directive. Its introduction, its emphasis on product safety and the inclusion of room for technological developments (i.e. nano-technology) signals the EU’s advanced and ambitious standards which make it the global leader. In contrast to the present arrangement where the Directive has had to be transposed into the national legislation of 27 countries, no transposition will occur with the Cosmetics Regulation, thus preventing member states from deviating from the official text in any way.

This chapter is divided into three parts. Part I examines the historical background to cosmetics legislation in the EU, including a brief history of cosmetics in the region. Also in this part, the harmonisation of cosmetics legislation among the EU member states is analysed. The factor underpinning harmonisation i.e. the trade barriers is also discussed. At the end of Part I, the advantages of the system are analysed. Part II moves on to analyse the implementation of the Directive in which

\textsuperscript{314}The collaboration between the EU and ASEAN has been through the ASEAN-EU Programme for Regional Integration (APRIS programme) to assist the ASEAN member states in strengthening the implementation of the ASEAN Cosmetic Directive especially on the technical assessment. (Detailed discussions in Chapter 5).


\textsuperscript{317}Risk and Analyst Limited, 2004, supra., p. 5. Certain futures mentioned are; first, the broad definition of a cosmetic, second feature is regulation of substances based on negative and positive lists and the third feature is the manufacturer responsibility for the product safety with in-market surveillance systems to monitor compliance.

\textsuperscript{318}Regulation 1223/2009 EEC.
certain activities or tools\textsuperscript{319} are used by cosmetics companies before marketing their products on the market. The activities conducted are the controls over the ingredients used in cosmetics as well as the safety and risk assessment of such products. The discussions will also comment on another method deployed in the cosmetic regulatory framework; the requirement on the manufacturers to compile a safety and maintenance data file. Information regulation and labelling requirements will also be evaluated as will post-market obligations which entail product withdrawal and recalls, and enforcement and reporting obligations. As the framework of the cosmetics safety in the EU has been explained in Part II, Part III further examines the issues regarding the actual implementation of the legislation in the EU member states, including the transposition of the Directive into the national legislations, the implementation of pre-market surveillance, and the handling of non-compliance cases. Lastly, as the EU Cosmetics Directive is now being replaced by the Cosmetics Regulation, some analysis of the new regulation including the significant changes from the current system will be made.

### 3.2 Part 1: Historical Background of EU Cosmetics Directive and the Harmonisation of Cosmetics Regulation

#### 3.2.1 A brief history of cosmetics in the EU

The earliest recorded evidence for the use of cosmetics in Europe goes back to the Middle Ages.\textsuperscript{320} For example, in Rome at that time, people used barley and butter to cure pimples while sheep fat and blood had been used to polish their fingernails. There were also mud baths and some Romans dyed their hair blonde as it was considered ‘angelic.’\textsuperscript{321} However, recipes for most of these were only mainly aimed at the upper classes. It is thought that some ingredients involved the use of poisonous materials such as white lead, a mixture of hydrate and copper – these were manufactured primarily in Italy and France. During that time, it was claimed that cosmetics posed a risk to health because they were likely to block vapours and prevent the efficient circulation of energy around the body. With time, hazardous

\textsuperscript{319}Some literature refers to these activities as ‘in-market’ control activities. However, for the purposes of this thesis, they will all be termed ‘pre-market’ activities since all of the activities are mandated to occur prior to the products being released on the market


lead and copper mixtures used as face powders were replaced by less harmful zinc oxide ones. Safe ingredients were also used. For example, talc was used as far back as the 17th century in England to make face powders. The importation of perfumes started to occur at this time from the Middle East. This marked the beginning of the scent-making industry in France, with perfumes nothing more that basic mixtures of natural ingredients.

3.2.2 Background of the EU Cosmetics Legislation

The 1957 Treaty of Rome gave 1969 as the year by which a harmonised EU market among the members of the European Economic Community (EEC) would be accomplished. However, the 1969 goal was considered too ambitious and the aim of harmonisation at that time was not achieved. In 1962, the European Cosmetic Toiletry and Perfumery Association, known as COLIPA was established. In 1965, COLIPA was also involved in preparing the introduction of the Cosmetics Directive. At the time, the proposed Directive was hailed as a major improvement on the legislation provision of many European countries. More importantly, it was considered as the first step towards the harmonisation of the cosmetics industry not only within the EEC, but also around the world. In 1976, the EU had finally established a single set of rules for cosmetics. The Directive, last amended in 2003, remains in effect until today. The contents of the Directive address issues specific to consumers as well as to trade and industry, within a general framework of safety.

An example that can be given is that labelling, packaging and safety rules must all be met before a product can be transported and traded within the internal

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322Ibid.
325COLIPA in its early form consisted of a Board of Directors and technical Committee and was a single liaison committee among 6 Member States Associations.
327There is a new EU Cosmetics Regulation (Regulation 1223/2009) which was passed on 30 November 2009 which will be replacing the current Directive. (Details of the new EU Cosmetics Regulation are explained in Part III in this thesis). It must be noted, however, that the Regulation is not available until July 2013.
This is one of the main objectives of the Cosmetics Directive; that is, to give clear direction on what safety requirements are needed before cosmetics can move unimpeded in the internal market without the need for prior approval. The guarantee that the Directive gives relates to the requirements of composition, packaging and information (pre-market system). The responsibility for complying with this falls entirely on those who put the products on the market. Post marketing surveillance is also part of the system and serves to monitor activities. The problems that the proposed Directive was designed to address at that time were essentially twofold: the need to remove barriers to trade in order to help in the creation of a Single Market in cosmetics; and the need to ensure that consumers are protected from any possible dangers to health posed by cosmetic products.

3.2.3 Barriers to trade

EU trade policy, by its very nature, promotes liberalisation. The thrust towards liberalisation culminated in the achievement of the internal market on 31 December 1992. This served to eliminate the remaining obstacles to trade. Here the internal market was achieved using two main tools: one is the elimination of some member states’ national restrictions on certain products and the other is the mutual recognition standards. The internal market benefited both the internal EU market but also other countries as well in the sense that it allowed easier access to the European market for the products of non-member countries. However, due to the difficulties that had arisen from the differing national requirements of each Member State, such trade barriers were regarded as the main hindrance to the efficiency of the open market in the EU. For example, each member country had its own definition of the word ‘cosmetic,’ which resulted in different procedures for the registration of cosmetic products. Another example is that in some countries, a business licence issued by a municipal authority needed to be obtained while in other countries one was not required. It was reported that another difficulty resulting from the trade

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331 Ibid., p. 10.
barriers was the necessity to register every single product or every single shade of colour of a single product.\textsuperscript{333} In some countries, products that fell under the category of cosmetics, such as hair dyes, were taken out of the cosmetics category as it was subjected to substantial additional requirements.\textsuperscript{334} Although all these were intended primarily for consumer safety, such differences have slowed the development of the cosmetics industry to an inefficient pace as such procedures often take a substantial amount of time.

\subsection{3.2.4 Harmonisation of Cosmetics Legislation in the EU}

In 1986, the Single European Act set 31 December 1992 as the new deadline for eliminating trade barriers. Progress made since 1986 has demonstrated that, substantially, this objective has been met. Against the backdrop of delay and intermittent forward movement, the harmonisation of cosmetic regulation in the EU stands out as an early and unusual, although somewhat qualified success. As mentioned, in the EEC’s early years, national regulation of cosmetic products was part of the larger problem of non-tariff barriers to free trade among the member states. There were significant differences not only in the technical provisions applicable to the composition of finished cosmetic products as well as to colourants and other substances used in cosmetics, but also in the definition of cosmetics categories in relation to categories for drugs.\textsuperscript{335} These differences in national regulatory schemes forced producers of cosmetic products to adapt their production practices to the different countries’ varying provisions.

The European Commission had simplified the European law on cosmetics and 27 sets of national legislation were replaced by one single directive. Its focus was to make products safer and reduce expenditure for businesses. For example, it has been claimed that by this simplification, administrative costs for enterprises were cut by as much as fifty percent.\textsuperscript{336} The Cosmetics Directive is the legislative framework for ensuring the safety of cosmetics. The transposing laws of the member states do not compare well with this well-structured and unifying system principally because their existence meant higher costs to industry with none of the benefits of greater safety. With the Directive, the Commission had essentially ensured a high level of safety of

\textsuperscript{333}Risk and Policy Analyst, \textit{op.cit.}, 2004, p. 25.
\textsuperscript{334}Ibid.
\textsuperscript{335}Further discussions are provided in the comparative chapter.
cosmetic products by compelling manufacturers to take responsibility in pre-market and post-market controls system for the producers while at the same time reducing unnecessary administrative burdens. This situation also created difficulties for regulators, because there was a chance that imported goods into particular member countries did not comply with local laws.

3.2.5 The Benefits of the Introduction of the EU Cosmetics Directive
The Directive clearly states minimum standards required of safety assessments and in so doing bolsters product safety in the internal market. Other safety measures include: stating the process involved when reporting undesirable effects, product withdrawal, and rules regarding coordinating enforcement procedures by the national agencies responsible. It must be remembered that one of the purposes of the Directive is the elimination of trade barriers in cosmetics through the harmonisation of different national laws. Under the Directive, the harmonisation of national legislation for cosmetics is achieved through the complete substitution of the EU provisions for the previously applicable national laws through maximal harmonization. Such harmonisation in the EU system has been of great help not only to the industry but also to the consumer as they will enjoy more choices of products.

Under the approach of the Cosmetics Directive and the harmonisation of the regulatory regime, differences in national legislation are eliminated. The chemical substances in cosmetic products are governed by a list of annexes to the Directive. The annexes specify prohibited and permitted ingredients, and consist of the list of prohibited substances, list of substances that are restricted and conditioned, list of permitted colouring agents, list of permitted preservatives and list of permitted UV filters. In addition, the Directive establishes a procedure of collaboration between the European Commission and the Member States that gives the go-ahead to the creation of standard analysis methods needed to check the composition and requirements for microbiological and chemical purity of cosmetic products. As a result of the Cosmetic Directive, EU member states are obliged to prevent the marketing of cosmetic products that do not conform to the Directive and to accept trade in cosmetic products that do. Consequently, the Directive both eliminates trade barriers

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337 Annexes of I – VIII of the EU Cosmetic Directive.
338 It must be noted that although it establishes the cooperation between the Member States, this in no way means that the enforcement is decentralized.
among the EU countries, and ensures that consumers are protected from cosmetics that are harmful to health or not properly labelled. According to Article 2 of Council Directive 76/768/EEC and its amendments:

'A cosmetic product put on the market within the Community 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, any instructions for its use and disposal 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 Community market.'

This article provides the key points for the production of safe cosmetics. This safety provision also emphasises that a cosmetic must not only be safe under normal but also under 'reasonably foreseeable conditions of use.' For this condition to be achieved producers must bear in mind several requirements such as presentation, warning labels, use and disposal instructions. In other words, the manufacturers, in order to produce safe cosmetics must adhere to the specific requirements of the Directive. These will be examined in the next part.

3.3 Part II: Analysis of the Safety Framework under the EU Cosmetics Directive

Introduction

Previously, it was explained that the EU Cosmetics Directive and the regulatory harmonisation created a new framework for cosmetics regulation within the EU. Before analysing the elements embedded in the EU cosmetic safety framework, first it will be considered how the term cosmetic is defined in this jurisdiction. This is because the overlapping product categories arise from the definition. The analysis of this part then followed by the background features of cosmetics safety legislation.

Note that there are the General Product Safety Directive (GPSD) provisions that are complementary to the Cosmetic Directive in case certain provisions are not covered by the Cosmetic Directive, such as matters relating to co-operation with the competent authority (GPSD Art. 5.4), adaptation of rules on penalties (GPSD Art 7), and RAPEX information exchange (GPSD Art. 12). Directorate General Health and Consumer Protection (DG SANCO), ‘Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety Directorate,’ November 2003
This includes the pre-marketing\textsuperscript{340} obligation as well as the post-marketing monitoring activities over cosmetics marketed in the EU. In the EU, pre-marketing activities are the process through which member states check that products, and thus the industry, are complying with the Cosmetics Directive prior to the product being sold to consumers. These activities, as specified under the Directive, fall into several areas. Firstly, control over the composition of cosmetics products to make sure that they do not contain any banned ingredients, or that they do not exceed the permitted concentration of restricted ingredients. Secondly, the requirements being placed on the manufacturers are divided into two; first, concerning the safety assessment of cosmetic products, and second, the maintenance of product data known as the Product Information File (PIF). The PIF should be complete for cosmetic products manufactured or imported into each country. Thirdly, verification that products are correctly labelled - including the language used, where appropriate whether the period for which the product should be used after opening is indicated, and any special instructions for usage.

As between the pre-market surveillance and the post market surveillance, there are claims that the latter activities are considered the more important method underpinning the systematic cosmetics safety legislation\textsuperscript{341} However, this has not been agreed by the European Consumers’ Organisation (BEUC). In their consultation papers on the new EU Cosmetics Regulations\textsuperscript{342} which is replacing the current Directive, they claimed\textsuperscript{343} that both pre-market surveillance and post-market surveillance are of equal importance. They were of the view that the current system, as well as the new Cosmetics Regulations, appears to give more focus to post marketing controls, i.e. the control that takes place after products have been placed on the market.\textsuperscript{344} They argued that ‘prevention is always better than cure.’ In another

\textsuperscript{340}As mentioned in the previous part, these pre-marketing surveillance activities are also known as the ‘in-market’ activities. However, to avoid confusion, only the term pre-market will be used throughout the thesis to illustrate the surveillance system prior to placing cosmetics on the market.
\textsuperscript{341}European Commission DG Pharmaceutical and Cosmetic, 1999, p. ii.
\textsuperscript{342}The EU Cosmetic Regulation 1223/2009 has been approved by the EU Parliament in first reading on 24 March 2009. It is scheduled to be implemented on July 2013. Part III of this thesis discusses the Regulation.
\textsuperscript{343}BEUC, ‘Cosmetic Should Not Harm: BEUC Position on the Commission Proposal for a Regulation on Cosmetics,’ Bruxelles, 2007, p. 16.
\textsuperscript{344}Ibid.
study by GHK Technopolis for European Commission conducted in 2007, one of the concerns raised in the EU was how did pre-market surveillance, particularly over cosmetic products, effectively protect the consumer. The study reported that although more than half of the respondents in the survey agreed that it did effectively protect the consumer, another significant minority felt that the system of pre-market surveillance in the EU was not protecting consumers effectively enough. Among the reasons mentioned were that the Cosmetics Directive contains insufficient detail concerning the operation of the system of pre-market surveillance; in particular the required scale and scope of checks, and procedures in the event of non-compliance.

This is particularly true that although harmonization standardised the rules to all member states, each operates very different systems, with some conducting pre-market surveillance more thoroughly and more effectively than others. Since cosmetic products were allowed to move freely within the EU, it was reported that that there was to a certain extent 'lax' pre-market surveillance in one member state which could affect consumers across the Community. Of course, member states could always identify non-compliant products during pre-market surveillance in their own country, but this variation in thoroughness is claimed to go against the spirit of high standards of consumer protection across the EU. Apart from that, the study also highlighted that a number of member states lacked sufficient internal capacity to carry out pre-market surveillance to the extent and depth that they would like to. Given the size of the cosmetics market, this meant that a fraction of products were being assessed. Romania was mentioned in the study as an example of a member state that had no laboratory facilities capable of carrying out tests on the chemical composition of products.

It should be highlighted that obliging manufacturers to carry out controls over the safety of cosmetic products before they are allowed to be placed on the market is the elementary procedure that is both essential and common to safety mechanisms.

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346The study held that 67% of the respondents agree to the questions. The respondents in the survey include the regulators, the national authorities, the cosmetic industry and the consumers. DG Enterprise and Industry European Commission, *ibid.*, 2007, p. 28.
for cosmetic products. As has been previously mentioned, only safe cosmetics are allowed to be placed in the EU market.\textsuperscript{350} This obliges producers/distributors to assume responsibility for their products’ safety under the ‘reasonably foreseeable conditions of use’ requirement.\textsuperscript{351}

3.3.1 Cosmetic products in the EU Cosmetics Directive: Definition of cosmetics

Art. 1(1) of the Cosmetic Directive defines ‘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.’

According to the definition, there are two cumulative aspects, first, the target part of application ‘placing on body/teeth/mucous membranes’ and second, ‘intended main (cosmetic) function’ (i.e. cleaning, perfuming, changing appearance, correcting body odours, protecting, keeping in good condition).\textsuperscript{352} The effect is that it attempts to establish parameters by describing common characteristics of products that are regarded by most people as cosmetics.

Concerning the definition, although it is a clear definition, similar to those in many jurisdictions,\textsuperscript{353} it raises the question of borderline issues with other products. Medicinal products are chief among those likely to be disputed. An example of this is skin cream. The basic function of such products is to lubricate the skin in order to help maintain its proper function. With this in mind, it clearly falls within the category of a cosmetic product because it is ‘...intended to be placed in contact with the various external parts ...with a view exclusively or mainly to cleaning them, perfuming them...’

\textsuperscript{350}Article 2 of the Directive. See earlier section.
\textsuperscript{351}Article 2 of the Directive.
\textsuperscript{352}Guidance Document on the Demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83
\textsuperscript{353}It is not only raised in the EU but also mostly in many other jurisdictions, USA for example has dealt with similar issue of borderline products. (The issue in USA regarding the borderline product is explained in Part III of Chapter 5 in this thesis.)
The definition is thus based on the parts of the body to which products are applied and the purposes for which they are applied. On the other hand, if the product is claimed to be an ‘anti-acne cream’ then it is no longer under the cosmetic product category, rather it is a medicinal product, which is treated under the medicinal product category.

In contrast to the ‘cosmetic’ product definition under the EU Cosmetic Directive, a medicinal product in the EU is defined under the Medicinal Products Directive 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 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 Cosmetics Directive had helpfully provided an indicative list by category of products that are considered as cosmetic products in member states in Annex 1: Illustrative List by Category of Cosmetic Products. It must be noted that the list in Annex 1 is, however, not exhaustive, so that other products may also fall under the definition of cosmetic products.

The essential implication from the categories suggests a totally different rule; that pharmaceutical products are subject to a more rigorous regulation. It is noted that pharmaceuticals are subject to a requirement for prior authorisation— they are not allowed to be placed upon the market until authorisation has been granted. Further, new pharmaceutical products will only be authorised if they meet the

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354 Directive 2001/83/EC
355 Art 1(2) of the EU Cosmetics Directive
356 The list specified are 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 product, anti-wrinkle products
criteria of efficacy, quality and safety. Apart from that, applications for authorisation must contain a full technical dossier covering both safety and efficacy, including data on clinical trials.

A medicinal product also requires the adoption of pharmaceutical Good Manufacturing Practice (GMP) rules when manufactured and they are also subject to limitations on advertising and distribution channels. In addition, sales of medicinal products in the EU are subject to rules (which differ between member states) limiting their sales to pharmacies, whereas cosmetic products are free to be placed on the market in the EU as long as the cosmetics companies ensure the safety of their product before marketing them.

As well as possible 'borderline' issues with medicinal products, there are similar issues with cosmetics and biocides products and also food. As for food, a good example is yogurt which claims to nourish the skin from the inside or the so-called collagen rich foods that claim to delay the ageing process. Realising the fact that the difficulties have arisen from these overlapping categories, the Commission has published a number of guidance documents to facilitate the application of Community legislation in these cases.

While it is true that there are several guidelines issued by the Commission to help member states to implement their policies, as well as for the industry to follow, it is also essential to stress that these guidelines serve merely as guiding documents per se, and they do not have any legal value or binding force. It is therefore submitted

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357 As for cosmetic, they only have to show that the product is safe for human consumption under the reasonable foreseeable condition of use.
358 In some countries, though, for example the UK and Germany, certain medicinal products may be freely sold.
359 Biocides products are defined in Directive 98/8/E 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'.
360 Sophie Goodchild, 'Beauty treatment you can dine out on,' Evening Standard, Thursday 10 February 2011
they can only be used as interpretive and preparatory tools.\textsuperscript{362} In conjunction with the borderline cosmetics and drugs issues, the European Court of Justice has made it clear that a product cannot fall within the definition of both categories at the same time. The case law\textsuperscript{363} spelt out, that in categorising a product within one category or another; consideration must be given to ‘the definitions within the relevant legislation but also of the description of the products themselves.’ Also, the relevant authorities and legal systems within member states have certain discretion in determining the product category based on a case-by-case basis. Although this has resulted in some variation in how products are categorised between member states, however the classifications emerge mostly similar for most products.

In one of the consultation papers on the Cosmetics Regulation which is replacing the current Cosmetics Directive, it is argued by the European Consumer’s Organization (BEUC)\textsuperscript{364} that the definition of ‘cosmetic’ in the existing Directive has caused many problems as it has caused confusion particularly in the overlapping product categories. They asserted the need for a substantial change in the definition. In the new Cosmetics Regulation\textsuperscript{365} which is replacing the current EU Directive however, no substantial change is noted with regard to the definition.

3.3.2 Controls over ingredients and safety assessments

As previously mentioned, ensuring the safety of cosmetic products is a crucial task in the EU as it is regulated by Article 2 of the Cosmetics Directive. The Directive concerns itself with the following safety features: presentation, labelling, use/disposal instructions, any other additional information made available by the producer or distributor. There are two different aspects of safety assessments addressed in the Cosmetics Directive; product safety assessments (including, but not limited to) the assessment of the safety of the ingredients as used in the product are under the main responsibility of the industry and secondly, the assessment of ingredients for the purpose of listing in the Annexes of the Cosmetics Directive.


\textsuperscript{363}For example, cases C112/89, Upjohn [1991] ECR I-1703. Also C-290/90 Commission of the European Communities v Federal Republic of Germany


\textsuperscript{365}Ibid.
These fall under the task mandated to the scientific committee appointed by the EU Commission.

One of the essential features of the EU Cosmetics Directive in ensuring the safety of cosmetics is by regulating the composition of cosmetic products. If, after testing, substances are found to be harmful under the intended use criteria they are not allowed to be used. Here, the task of advising the assessment of the composition/formulation is given to an appointed scientific committee; namely the Scientific Committee on Consumer Products (SCCP).\textsuperscript{366} The SCCP’s task is to provide the EU Commission opinions on questions regarding the safety of consumer products, specifically non-food products. In particular, it is tasked with providing opinions in relation to the safety and allergenic properties of cosmetic products.\textsuperscript{367} Therefore, the Commission will consult with the Committee on specific issues as they appear which they believe could be hazardous to consumer health.\textsuperscript{368}

Under the Cosmetics Directive, prior approval is not required for produced or imported products, except for certain specific substances used in cosmetic products, such as colourants, UV filters and preservatives.\textsuperscript{369} The Directive also exercises the series of lists of prohibited,\textsuperscript{370} restricted\textsuperscript{371} and permitted\textsuperscript{372} substances which are called the Annexes to identify which substances are allowed, or not allowed in certain products. Annex II for example, lists more than 1000 substances (1328 to the present day) that are prohibited for the use in cosmetic products. The list in Annex III is for substances which can only be used in particular products or must be labelled in a certain way, these include for instance, hydrogen peroxide and aluminium fluoride. Annexes IV, VI and VII list approved colourants, preservatives and UV filters,

\textsuperscript{366}This Committee is appointed in accordance with Commission Decision 2004/210/EC.
\textsuperscript{367}Also cosmetic ingredients with respect to their impact on consumer health, toys, textiles, clothing, personal care products, and domestic products such as detergents and consumer services such as tattooing.
\textsuperscript{368}\textit{Ibid.} Analysis of the SCCP’s roles and responsibilities are explained in the next section.
\textsuperscript{369}Colouring agents (with the exception of hair dyes) (Annex IV), preservatives (Annex VI), and sunscreens (Annex VII) can only be used in cosmetic formulations if they are listed in the Annexes and used according to the conditions given therein.
\textsuperscript{370}Annex II is the list of substances which must not form part of the composition of cosmetic.
\textsuperscript{371}Annex III is divided into two parts. Part 1 is the list of substances which cosmetic product must not contain except subject to restriction and condition laid down. Part 2 is the list of substances provisionally allowed.
\textsuperscript{372}Annex IV, part 1 is the list of colouring agents allowed for the use of cosmetic whereas Part 2 is the list of colouring agents provisionally allowed in cosmetic products.
respectively. It is important to note that only colourants, preservatives and UV filters listed in approved list of the Annexes may be used in cosmetics products.373

3.3.2.1. The Scientific Committee on Consumer Products (SCCP)
As mentioned earlier, in the EU, the evaluation of the safety of cosmetic products is carried out by the Scientific Committee on Consumer Products (the SCCP), a body that was previously known as the Scientific Committee of Cosmetology (the SCC). The Committee evaluates the substances in Annexes II,374 III,375 IV,376 VI,377 and VII378 of the Directive. The other Annexes fall under the responsibility of the manufacturer through the safety assessor appointed by the manufacturer. In general, the safety evaluation of cosmetic ingredients by the SCCP is based upon the principles of the risk assessment process.379 The Committee is one of the three independent non-food Scientific Committees managed by the Directorate General for Health and Consumer Protection (SANCO) of the European Commission. In 1982,380 prior to the implementation of the Sixth Amendment,381 guidance entitled ‘Guidelines for the Toxicity Testing of Cosmetic Ingredients’ was published by the SCC. Subsequent publications followed which demonstrated the advances in the field of toxicology, and in particular the ability of the SCC/SCCNFP to evaluate cosmetic ingredients.382

Note that these lists are not exhaustive.

Annex II is the list of substances which must not form part of the composition of cosmetic

Annex III is divided into two parts. Part 1 is the list of substances which cosmetic product must not contain except subject to restriction and condition laid down. Part 2 is the list of substances provisionally allowed.

Annex IV, part 1 is the list of colouring agents allowed for the use of cosmetic whereas Part 2 is the list of colouring agents provisionally allowed in cosmetic products.

Annex VI contains the list of preservatives which cosmetic product may contain.

Annex VII, part 1 is the list of preservative allowed, and part 2 is the list of preservative provisionally allowed.

The risk assessment procedure is subdivided into four parts, first is hazard identification, second is dose-response assessment, and third is exposure assessment and lastly the risk characterisation. Reference to SCCP Notes of Guidance for the testing of Cosmetic Ingredients and Their Safety Evaluation, 7th Revision, 14 December 2010, EC Health and Consumer Protection.

Report EUR 8794.

93/35/EEC.

At present, safety evaluation of cosmetic ingredients is carried out by the SCCP using data obtained from animal studies (in vivo), in vitro experiments, QSAR (quantitative structure activity relationship) calculations, clinical studies, epidemiological studies and accidents.
3.3.2.2. The SCCP’s Establishment and Role

The Scientific Committee on Cosmetology (SCC) was initially established on 19 December 1977. Its role was in a technical and scientific capacity working for the European Commission on problems relating to the composition, production, packaging, and labelling of cosmetics for the internal market. The Committee was created afresh every three years. The Committee was renamed in 1997, and became the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP). The Committee was made up of independent experts from many medical fields such as: pharmacy, biology, toxicology, dermatology, and chemistry. The SCCNFP fulfilled its function of evaluating the safety of cosmetics until 2004 when it was replaced by the Scientific Committee on Consumer Products (SCCP). This was part of a larger restructuring of the Scientific Committees dealing with the environment and consumer health and safety. Commission Decision 2004/210/EC specifies that:

‘[T]he SCCP shall provide opinions...in particular it shall address questions in relation to the safety and allergenic properties of cosmetic products and ingredients with respect to their impact on consumer health...In addition, the Commission may request advice from the Committee on any other matter in the field of its competence.’

Based on the provision, the SCCP’s task can be divided into two main categories, namely matters relating to cosmetics ingredients and products and those relating to other non-food consumer products. As for the cosmetics ingredients, the consultation of the SCCP is mandatory, whereas it is not compulsory in the non-food products category. This provision mandates authority to the SCCP as the competent body that carries out the proper assessment of the risk of the substances which can be posed by their presence in cosmetic formulations. Most of the matters advised by the SCCP concerning cosmetics ingredients are taken by the EU

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383 Commission Decision 78/45/EEC.
384 Established by Commission Decision 97/579/EC.
386 Commission Decision 2004/210/EC.
387 As stated in Art. 8.2 of the Cosmetics Directive [76/768/EEC].
Commission. The SCCP opinions are adopted in the technical adaptations in the Directive.

In addition, the SCCP has published a guidance document for the testing of cosmetics substances and their safety assessment.\footnote{DG of Health and Consumer Protection, ‘7th Revision of the SCCP Notes of Guidance,’ op.cit.} The document contains relevant information on the different aspects of testing and safety evaluation of cosmetics ingredients. It is designed to provide guidance to public authorities and the cosmetics industry, in order to improve harmonised compliance with Directive.\footnote{Ibid., p. 2} However, it should be remembered that their guidance document is not mandatory.

It has been claimed by the EU Consumer’s Organisation or BEUC\footnote{BEUC, supra, 2007, p. 16.} that the guidelines and rules provided are not strictly followed either by industry, due to their non-binding nature, or, by national authorities because the technical dossier\footnote{The Dossier is a compilation of documents designed to verify a product’s safety and must include a safety assessment. It is not submitted formally prior to marketing, but must be available on request by the Member states local health authorities. Dossiers are reviewed and assessed by safety assessor who is qualified under each member state’s regulation.} provided to them by the industry is often not specific enough. Due to that, the organisation has therefore called for the guidance documents to be made mandatory, and that the guidelines produced by the SCCP should be turned into legislation.\footnote{See BEUC, 2007, pp. 6-8.}

Considering the view of the BEUC, it can be seen that although the guidelines provided by the SCCP have no legal force, they are still followed by the industry. However, the argument brought up by the BEUC to make them mandatory and be turned into legislation is thought to be very relevant because at present the only general reference point is Chapter VI of the SCCP guidance as it specifically deals with the safety of cosmetic products.\footnote{Chapter VI, Notes of Guidance for Testing of Cosmetic Ingredients and Their Safety Evaluation by the SCCP, op.cit.} In it, it outlines the procedure it considers should be followed for safety assessments of cosmetic products prior to being placed on the market. It is significant that this suggested guidance is not, in the main, followed as has been shown in research commissioned by DG Enterprise and Industry. It was reported that the statistic which really stands out is that about 40% of all cosmetics safety examinations are considered to be inadequate or incomplete by the competent authority.\footnote{GHK, ‘Evaluation of the Cosmetics Directive, supra, Chapter 5.1.}
Another study has indicated that a number of member states argued that the SCCP as an independent expert body is invaluable and acts as a ‘much-needed mediator’ between governments and the cosmetics industry.\textsuperscript{395} This was particularly true of those member states that were the most ‘active’ in terms of investigating cosmetics ingredients and products. However, the study reported that many respondents suggested that the process through which ingredients are evaluated and potentially included within the Directive is much too slow.\textsuperscript{396} It was insinuated that this could take several years where the scientific evidence is disputed by industry, during which time most ingredients under suspicion usually remain in use. This was seen by competent authorities and other national authorities to be one of the least effective areas of the Directive, and one that could potentially put consumers at risk.\textsuperscript{397}

\subsection{3.3.2.3. Safety assessor}

Earlier, it was explained that the essential characteristic of the EU Cosmetics Directive in ensuring safety of cosmetic is by regulating the composition of cosmetic products where the task of carrying out these assessments falls to the SCCP. While the SCCP, as an independent expert scientific committee, advises the European authorities on safety assessment and the safety of individual ingredients, another important element in ensuring safety of cosmetic products in the EU according to the Directive is that, all cosmetic products on sale in the EU must go through safety assessments provided by a qualified safety assessor. These assessments cover the safety assessment of substances or combination of substances based upon their human exposure evaluation in the finished product, their chemical structure and profile, as well as their general toxicological properties. In its reasoning, a safety assessment also includes confirmatory safety information on the finished product and post marketing safety experience, its presentation and method of use.

Safety assessments require much greater expertise than just the compilation of toxicological data in the form of a predefined list. Pre-market control of the safety of cosmetic products and their ingredients would not benefit from a rigid list of obligatory tests on each individual ingredient in the product information file. The

\textsuperscript{395} DG Enterprise and Industry European Commission, London, 2007, p. 35
\textsuperscript{396} Ibid.
\textsuperscript{397} Ibid.
kind of information required to be compiled for safety assessments of ingredients is
dependent to a large extent on the type of product, its presentation, intended user,
the ingredients’ chemical and physical properties and their concentration in the
product. In this sense, the chemical safety data of the single substances are compiled
and verified.

The safety assessor, according to the Directive, can be any person with a
qualification in a relevant field such as ‘a diploma in the field of pharmacy, toxicology,
dermatology, medicine or a similar discipline and be suitably trained in the safety
assessment of cosmetics.’ The safety assessor should determine if the ingredients
in the cosmetic formula are legal in general terms, in concentration, and in the
absence of prohibited substances. He or she needs to identify if the data available is
relevant and sufficient. He or she is also responsible for determining if any of the
ingredients are likely to react with one another in a harmful way or if there are likely
to be modifications to penetration, as well as for recommending if any additional
data is required either on ingredients or on the finished product.

The ‘Notes of Guidance for Testing of Cosmetic Ingredients and Their Safety
Evaluation’ which has been published by the SCCP could be the key guidance for
the safety assessment. The document includes relevant information on the different
aspects of testing and the safety assessment of cosmetic components. Not only is it
designed to provide guidance to the industry but also to public authorities. This
fundamental approach is transparent and well understood by both industry and
competent authorities and creates an appropriate basis for consumer confidence.

3.3.3 Requirements on manufacturers concerning safety and maintenance
of data files (PIF)

The second important tool that has been implemented under pre-market control of
the current Directive is the requirement for the manufacturer to provide the data
files on the safety of the cosmetic products it has produced. The Sixth Amendment of
the Directive also included a number of other safeguards in relation to giving an
inventory of ingredients in products. Bans on marketing testing on animals have also
been introduced. It provides that the ‘Commission shall compile an inventory of

398 Article 9 of the Directive.
399 SCCP Notes of Guidance, supra. Note that this guidance however has no mandatory effect.
400 93/35/EEC

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ingredients used in cosmetic products, based on particular information supplied by the industry concerned. These improvements necessitate the cosmetic companies to keep the safety information readily available for the competent authorities. The data required to be put in the PIF files according to Article 7 of the Directive are the ‘assessment of the safety for human health of the finished product; as well as the name and address of the qualified person responsible for the assessment, the qualitative and quantitative composition of the product, the physico-chemical and microbiological specifications, the method of manufacture complying with the good manufacturing practice (GMP), existing data on undesirable effects on human health, proof of the effect claimed for the cosmetic product and data on any animal testing.’

Based on the above provisions, this mechanism essentially provides a short cut to the listing by the manufacturer of extensive data on ingredients, in that it permits or bans certain listed ingredients to be used based on pre-existing toxicological testing and assessments that need not be repeated or documented when approved ingredients are used in particular products. Concerning the responsibility placed under the Directive, there is considerable flexibility allowed as to who has the responsibility of keeping the specified information. It may be ‘the manufacturer, or his agent, or the person to whose order a cosmetic is manufactured, or the person responsible for placing an imported cosmetic product on the Community market.’ Therefore, there may be some confusion about who is actually holding the specified information, particularly where a manufacturer and a third party is involved, and there may be some difficulty in enforcing such obligations. In any event, the information is also to be kept at the address specified on the product’s required label.

Although the requirements are somewhat thorough, a report by the DG Enterprise and Industry of the EU Commission insinuated that there is no set template for the contents of a PIF, and consequently Member States have no point of reference against which to judge compliance. As noted above, there are also considerable differences in the approaches taken by competent authorities towards assessing PIF, making it hard to draw overall conclusions about non-compliance in

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402 There is however no definition of this term in the Directive.
403 Directive 76/768/EEC art 7 article 1
405 Ibid.
this area. For example, it was shown in the said report that a proportion of PIF checked by the competent authorities in the previous years were judged to have failed to meet the requirements of the Directive. In this report, it was also found that the PIF requirements, compared to other pre-market requirements specified in the Directive, are the least clear as there is no set template for its contents. Consequently the available data is claimed as ‘patchy,’ a few Member States have reported that since they did not carry out checks systematically there are no figures available for the number of PIFs found to be non-compliant. In addition, it was also reported that there were many instances of incomplete PIFs, most frequently lacking was information on the safety assessments carried out on the product a failure to provide sufficient information about the raw ingredients. On occasion, competent authorities reported that PIFs were not available at all, particularly where products were imported from outside the EU by small firms.

Again, there was considerable variation between Member States in the proportion of PIFs judged to have failed to meet requirements. Given the nature of PIF checks this is not surprising. The report mentioned that very few countries that systematically verify that PIF meet the requirements of the Directive. Instead, these checks are often initiated where a product is suspected to have failed to meet the Directive due to its chemical composition which usually resulting from a specific consumer complaint. Moreover, since the Directive is not explicit about what constitutes non-compliance, national authorities have the ultimate say on whether PIF breach the Directive. Apart from that, the approaches taken by Member States in the event of an incomplete or missing PIF also vary. Competent authorities tended to impose a deadline for the file to be revised, and in most instances this was deemed sufficient. In some cases, however, products were removed from the marketplace while the PIF was revised, depending on the severity of the breach which was based on the nature of the information missing. Bulgaria and the Czech Republic were given as the examples, where it was reported that financial penalties might also be imposed on the offending firm, (depending on the severity of the breach), while the French authorities reported that they routinely assess PIF as part of pre-market surveillance. Furthermore, they (French authorities) are usually very strict where a

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406 The countries reported are Denmark, Austria and Slovenia, ibid., p. 20.
407 Ibid.
408 Examples reported are as high as 100% in Romania and as low as 14% in Cyprus, ibid., p. 41.
409 The report however did not mention which countries.
PIF does not contain the information required, and regularly contact the manufacturer or importer in question to insist on the correction of the problem. Where this is not resolved, the authorities have in the past insisted on the withdrawal of the product concerned from the marketplace.

Although the above reported data was taken a few years back and there is no available current data, the situation does not seem to have changed much. In fact, the EU Consumers’ Organisation (BEUC), shares the same view that the requirements of PIF data are vague and insufficient. They do not only claim that the PIF requirements should contain technical and scientific data in greater detail, but also assert that other specific data should be included if products are intended to be used by vulnerable populations, including children and pregnant women, and also if products are to be used in sensitive areas of the body such as on the lips and mouth, and around the eyes or genital region.

While it appears that the Directive’s requirements contained in PIF could be considered insufficient, the cosmetics industry however, had a different view. The industry was dissatisfied with some of the provisions in the Directive that its existing data on undesirable effects on human health resulting from use of the cosmetic products be disclosed. Although it is understood that the purpose of the requirement is to help the public to assess the safety of the product, however, consumers have other ways of understanding and processing information and this can lead to the dissemination of unreliable information which could harm the reputation of the manufacturer in question. Furthermore, cosmetics are the only consumer products that have been burdened with this obligation, no other products have this requirement - not even drugs, that in general, are regulated by much stricter safety rules.

In helping the industry to deal with this situation, COLIPA has published Guidelines on the Management on the Undesirable Event Reports with the aim of ‘minimising differences in the implementation of the current regulation by giving broad instructions to the cosmetics industry on receiving, centralising, recording, and analysing genuine undesirable event reports.’ The guidelines specified that only those undesirable events or effects linked to normal or reasonably foreseeable

410BEUC, op.cit., p. 15.
411For example the data to justify the ‘period of opening’ and expiry date details.
413Ibid.
uses of a cosmetic product are considered in the report. However, reports linked to product abuse or misuse, whilst also relevant for cosmetic manufacturers, fall outside the scope of this document. The issuance of the COLIPA Guidelines complements the GPSD’s Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers and Distributors. These Guidelines by the GPSD give guidance on the criteria to facilitate effective application of the producers and distributors obligations for the purposes of risk managements.

In short, the issue of PIF is claimed to be one of the main problems affecting the application of the Cosmetics Directive in the EU. The system at present is widely considered by Member States not to be operating effectively. For example, data provided by competent authorities was reported that on average over half of all PIFs do not comply with the requirements of the Directive.

Furthermore, it has been asserted that the system whereby PIFs are only kept in the country of manufacture or importation and then made available to other Member States on request is not working well. Requests for PIFs have been reported to take months to be answered, again impacting on the work of the competent authorities. These problems have in part arisen because of a lack of clarity within the Directive regarding exactly what information manufacturers or importers should include within the PIF, thus making it hard for Member States to impose punishments where the file failed to provide them with the information they needed. The public consultation exercise being carried out by DG Enterprise and Industry also invites consultees to comment on this issue, and there is widespread support amongst competent authorities for changes in this area. The problems experienced by Member States when seeking to obtain a PIF from another competent authority are more complicated, and the fault is believed to lie with national governments. Again, however, the Cosmetics Directive are suggested that it could be more explicit

\[\text{Ibid.}\]
\[\text{Product used which is not in accordance with the intended purpose and the correct conditions of product use and/or with the directions of use and/or with specific warnings mentioned on the product. See page 6 of the Guidelines.}\]
\[\text{In which they are classified separately.}\]
\[\text{Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers and Distributors In Accordance With Article 5(3) Of Directive 2001/95/EEC}\]
\[\text{DG Enterprise and Industry European Commission, 2007, pp. 40-42.}\]
\[\text{Ibid.}\]
in this regard (for example by setting a time limit for a reply), or it is possible that a single centralised location for storing PIF could be set up. This calls for a more wide-ranging platform for information sharing (particularly the PIF). The contents of the PIF should be set out in greater detail in the text of the Directive in order to provide manufacturers with clearer guidance, and to provide competent authorities with a template against which to compare actual PIF (and thus act upon non-compliance).

3.3.4 Labelling requirements

Labelling is another important element in the EU pre-market control of cosmetics framework. Cosmetic products may only be marketed if “their packaging, containers, labels bear the required information in indelible, easily legible and visible lettering.” The information that is required according to the Directive includes the name and address of the manufacturer or person responsible for marketing the cosmetic product; the quantity of the contents at the time of packaging, given by weight or volume; the date of minimum durability; the precautions to be observed in use, especially those listed as conditions of use and warning in the annexes and the batch number. Further, Article 6 of the Directive also sets out labelling requirements which, amongst other things, specify that ingredient lists must use the International Nomenclature of Cosmetics Ingredients (INCI). Member States can also require that certain pieces of information on the product labels should be expressed in their own official language(s).

Having examined the efficacy of the labelling system that is provided under the Directive provisions, the previous mentioned study by the competent authorities of the member states in the EU indicated that the most common ways in which products did not meet the labelling requirements of the Directive were; labels

421 Article 6 of the EU Cosmetic Directive.
422 Ibid.
423 On 8 May 1996 the Commission accordingly adopted Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products. The inventory and the nomenclature were to be in use from 1 January 1997. On 9 February 2006 the Commission adopted Decision 2006/257/EC amending Decision 96/335/EC in order to update the inventory and common nomenclature of ingredients employed in the cosmetic products set out in the Annex to Decision 96/335/EC. Decision 2006/257/EC was published in the Official Journal of the European Union on 5 April 2006. The discussions with the Member States and representatives of the cosmetics industry enabled 1 February 2007 to be set as the economically and technically feasible deadline for the use of the updated inventory and nomenclature. From this date, under the terms of Article 6(1) (g), sixth paragraph, of the Cosmetics Directive, the labelling of cosmetic products placed on the market must comply with the inventory and common nomenclature arising from the update laid down in Decision 2006/257/EC.
were not translated into local languages, ingredient lists did not make use of the INCI system, ingredient lists were not complete, product precautions were missing, and that manufacturer or importer details were missing, or did not match the information given in. The study also indicated that the rates of product labelling compliance vary significantly between Member States. The Cosmetics Directive appears to be explicit about the labelling that cosmetics products should use, and there should supposedly be little chance of inconsistency. The reality, however, according to a further report, held that Member States tend to overlook breaches that they do not consider represent a significant threat to consumer health, or which are seen as disproportionate to the effort associated with correction. The Danish authorities, were cited as an example in that they usually ignore minor spelling mistakes (such as in the ingredient list), but did always consider the absence of a registered address for the manufacturer or importer or no Danish translation of instructions to be a problem that needed to be corrected.

It should also be noted that a balance is required between protecting consumers and creating a favourable environment for businesses to operate in, in what is a highly competitive industry such as cosmetics. Approaches taken by Member States where products were found without correct labelling also varied according to the severity of the breach. For example, most Member States reported that minor breaches were usually ignored, or dealt with in a less strict manner, for example, with the imposition of a generous deadline for correction. However, where the offence was more serious, such as a lack of manufacturer or importer details, or a failure to translate instructions into the local language, then a stricter penalty was imposed. Again, this usually consisted of the imposition of a deadline for the correction of the product labels, but on occasions this was reinforced by the

425 It was mentioned that in Slovenia, for instance, products were analysed and found to include UV filters, preservatives and fragrances that were not listed as ingredients. In a number of cases this included known allergens. Ibid., p.39.
426 It was reported in the study that over the three years from 2004 to 2006, for instance, just 3% of products that were tested were found not to meet the labelling requirements of the Directive in Slovakia, but in France over the same time period the proportion was 73%. These results were suggested due by the fact that the Member States had adopted somewhat different approaches to product testing, and even to the criteria used to judge non-compliance. Ibid., pp. 39-40.
427 RPA 2004, p. 79.
428 Ibid.
compulsory withdrawal of the product from the marketplace, or even the imposition of a financial penalty.

Although it seems that labelling requirements are considered clear compared to the PIF’s detailed requirements (as mentioned in the former section), there are also some concerns raised by consumer organisations about this. Apart from requesting more detailed labelling of certain elements such as imposing a mandatory requirements to indicate the list of ingredients on the product itself rather than on the packaging alone, they also have also asserted that the legislator should introduce a mandatory labelling of both the expiry date (i.e. use by or best before DD/MM/YY) and the Period of Opening, i.e. after opening, use within X months. They also stressed the importance of having specific precautions of use - for example products such as hair dyes should bear the warning ‘This product should not be used by children under XX’, or ‘Keep out of reach of children.’ More importantly, they have stated that a specific warning should be introduced for products that may cause allergies, for example hair dyes. Indeed, it is a fact that the SCCP and an allergy research centre have shown that hair dyes may cause allergic reactions, and in certain cases potentially fatal ones. They have suggested that it should be made obligatory for the manufacturer to apply a clear, visible warning on the front of the packaging of such products of the same size as warnings on cigarette packs.

Another issue that needs to be discussed is the presence of misleading claims on cosmetic products. Although this falls under the purview of the advertising authority, it is also important to impose rules on the cosmetics industry to avoid misleading claims and in the end it helps to caution the consumer about their safety. This is due to the fact that often cosmetic companies make ‘pseudo-scientific claims,’ that is, assertions of scientific evidence that are vague rather than precise, and that

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429 Latvia was cited as an example in the report.
430 Such as in Bulgaria, France and Slovakia.
431 Another example of product that can cause allergy reaction is hair removal products.
433 For instance, the Danish National Allergy Centre. Mentioned by the BEUC, ibid., p. 13.
are difficult to measure. One of the examples given was the product introduced by Clarins called ‘Expertise 3P (Poly Pollution Protection),’ which was claimed to contain ‘Magnetic Defence Complex that protects skin against all type of pollution, including artificial electromagnetic waves.’ Regarding this claim, the UK Advertising Standard Authority (ASA) issued adjudication\textsuperscript{435} in August 2007 asking Clarins not to make such a statement unless they had robust scientific evidence to support it.

3.3.5 Post-marketing obligations

3.3.5.1. Post marketing responsibility by cosmetics manufacturer in ensuring safety

Introduction

The EU Cosmetics Directive provides post-market tools to supplement pre-market tools. As mentioned in the previous part, the data collection files, known as the PIF, are one of the important requirements under the pre-market surveillance tools that must be maintained by the manufacturers. The requirements in the PIF system have been explained; however another important element in PIF is its use as a post market tool. The responsibility of the manufacturer is to keep and make accessible data on undesirable effects on human health resulting from the use of its cosmetic products. This can be the safety information reported by users, retailers, distributors, regulators, or any other source, including scientific and technical literature; on how safe the product is in practice and whether it continues to conform to the standards of safety as these evolve in light of new scientific and technical information. The rationale of this system is to guarantee that the new safety information is kept in proper custody, so that there is a complete and recent body of safety information that adds to the pre-marketing predictions and assessments, by providing information from the actual use, and on which an ongoing reliable reassessment of safety can be made. This is covered by the EU Cosmetics Directive, under Article 7a(f). However, no specific details are provided concerning how long such information should be kept. It is suggested that in practice, such information is likely to come from scientific sources and consumer complaints\textsuperscript{436}

\textsuperscript{435}The Advertising Standard Authority (http://www.asa.org.uk/) is an independent body that polices rules laid down in the advertising codes. The adjudication can be found at: http://www.asa.org.uk/asa/adjudications/Public/TF_ADJ_43024.htm (last accessed 20 February 2011).

\textsuperscript{436}RPA, 2004, p. 89a.
In addition to the system of keeping and making information available and accessible, product or batch marking is another measure to enable the cosmetics producers to be informed of risks. It may be that not all products are dangerous to consumers, but only some of the items placed on the market. The hazard may only be particularly related to some of the products of a certain batch. In such cases, consideration should be made to the probability of such a hazard being present, and in which products. Therefore, batch marking helps identify the products and producers easily. Indeed, product or batch marking can facilitate the effective product recall of a specific identifiable batch, thereby avoiding recalling all items unnecessarily. Under the EU Cosmetics Directive, a batch or code number is required to be marked on each product on both the primary container as well as the outer packaging.\textsuperscript{437} It enables the manufacturer or supplier to identify the batch in which the product was manufactured. This is good practice for cosmetics as batch marking is a relatively precise way of ensuring traceability. Through this, if a problem should arise, the quantities of the products that have to be recalled or 'held' in stock pending further investigation can be limited.

3.3.5.2. Cosmetic withdrawal, recalls and the RAPEX Notification

In the EU, public authorities play an active role in taking appropriate action. This may include the withdrawal and recall of cosmetics. Cosmetic products that do not comply with the EU legislation are considered unsafe and can therefore be withdrawn and recalled from the EU market. Withdrawals of cosmetics means the cosmetics (or the batch) affected that are in retail shop/shelves are removed. The removal is either done voluntarily by the cosmetics company after it has been found non-compliant with the Directive requirement. Withdrawal can also be ordered by the authorities in cases where the cosmetics company is reluctant. It has been reported through the RAPEX\textsuperscript{438} data analysis, the EU alerting system for dangerous consumer goods, that in the first trimester of 2011 alone, more than 20 cases of

\textsuperscript{437}Article 6 1(e). In the practice of the UK, it is recommended that where it is impossible, for reasons of size (note that many cosmetic products are in small sizes), to put the details of the batch code to appear on both the primary container and the outer packaging, then details is allowed to be given on the outer packaging only. See Cosmetic Safety: Guidance on the Implementation of the Cosmetic Products (Safety Regulation), 2004, DTI, April 2005.

\textsuperscript{438}RAPEX is the system for the rapid exchange of information arising from the use of consumer products, it was established in 1984- Council Decision 84/133/EEC, and this entered into force on 7 March 1885. This was subsequently replaced by Decision 89/45/EEC: OJ L 17/51 as amended by Decision 90/352/EEC.
incompliant cosmetic products were reported by EU authorities.\textsuperscript{439} In many cases, the content of restricted/prohibited substances was the reason for the withdrawal of the product. Some examples of recalled products include skin cream containing too much hydroquinone and hair colour containing the forbidden colourant ‘Basic Red 2.’ Product recall is set in motion when the competent authority believes that a harmful cosmetic has already reached consumers and when voluntary action has failed to remedy the problem.

It must be noted that both cosmetic product withdrawal and recalls are subject to the European Community General Product Safety Directive (GPSD). In the EU, the 2005 Directive\textsuperscript{440} gives the authorities the power to do mandatory recalls on dangerous products as it specifies that ‘recall obligation means any measures aimed at achieving the return of dangerous products that have already been supplied or made available to consumers by the producer or distributor.’\textsuperscript{441} In recent years a number of cosmetic products have been recalled from the European market due to the inclusion of hazardous chemicals, as highlighted by RAPEX. The example is the discovery of a substance called ‘Dibutyl Phthalate’ (DBP) in certain cosmetic products such as nail polish.\textsuperscript{442} This substance is listed under Annex II of the Directive (i.e. list of substances which must not form part of the composition of cosmetic products).\textsuperscript{443} Another example is the existence of too high a concentration of ‘Hydrogen Peroxide’ (listed in Annex III of Cosmetics Directive) that has been found in dental whitening products from Belgium. The SCCP has studied the effect of the substance when exceeding certain concentrations and concluded that it can cause irritation of eyes, skin, the inside of mouth, stomach, and intestine.\textsuperscript{444}

RAPEX notifications are disseminated across all competent authorities in the EU, thus ensuring that all Member States are made aware of any problems. The responses of the authorities to these notifications vary according to national law, although unsafe products must not be allowed on the market. The EU introduced

\textsuperscript{439}It is available at http://ec.europa.eu/consumers/dyna/rapex/create_rapex.cfm?rx_id=158, (last visited 8 April 2012).
\textsuperscript{440}The earlier General Product Directive (Directive 2001/95/EC) has no the power to require mandatory recall
\textsuperscript{441}Article 2(g) of the EU Directive.
RAPEX in 2003, and it publishes notifications on products including cosmetics that pose a health threat for the consumers which can be bought in EU market. It is noted that almost every notification published leads to a withdrawal or recall of the product from the market.445 All notifications from 2005 onwards can be found on the RAPEX website.446 Not only is there a reason given for the notification, there is also information about the product (name, brand, notifying country and the country of origin) given on the website. Consumers can carry out keyword searches on the website to search the notifications.

A study by Lundov and Zachariae447 has explored recalls of microbiologically contaminated cosmetics in the EU from 2005 to 2008. The study highlighted that ‘the number of contaminated cosmetic products could be two to three times higher in 2008 compared to 2007.’448 The study has highlighted the importance of monitoring contamination in cosmetics because the number of products recalled rises every year.449

As far as products recalls and RAPEX notifications are concerned, it was argued by the European Consumer Association (BEUC)450 that such methods are not particularly adequate for cosmetics. The reason for this is that often these products have already been used several times by the consumer before a problem is detected and tackled, therefore according to them, recalls of cosmetics have little impact on safety.451 Furthermore, it can be argued that in terms of practicalities, recalls are far from efficient. With consumer products, including cosmetics, the chances of getting the products returned are very small.452

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445See http://ec.europa.eu/rapex. Also, note that according to the GPSD, withdrawal and recalls are differentiated. A withdrawal is the removal of products by a supplier of product/material in the supply chain whereas a recall involves product that has been sold to the consumers or is with the end retailers and available for sale.
446See http://ec.europa.eu/rapex.
448Ibid, p. 471. The study however did not mention the reason behind the increment of the data.
449Ibid. According to the study, the majority was contaminated with potential pathogenic microorganism.
450BEUC, op.cit., 2007, p. 16.
452Based on a conversation with a legal practitioner (dated 26 January 2011) who works closely with the cosmetic industry. He is of the view that in so far as cosmetic recalls are concerned, no more than 10% of the products are ever returned.
3.3.5.3. **Cosmetic Databases**

Another tool provided under post marketing surveillance is the online cosmetics ingredients databases. Compared to RAPEX notification which is available for the public, this database was launched by the Commission for the cosmetic manufacturers to help them ‘find up-to-date data on ingredients wanted to make new cosmetics or to improve existing ones.’ The new database, called ‘CosIng’ (from the words COSmetics INGredients), replaces the old ‘pdf’ format list which was one of the most consulted documents on the DG Enterprise website.\(^{453}\) Cosmetics companies and authorities can check whether substances are regulated by the EU, whether restrictions are in place for any of these, but also SCCP opinions and current authorisations for the following: colourants, preservatives, and UV-filters.

The existence of this database means that cosmetics companies no longer have to search through a range of documents to get relevant data of an ingredient. Due to this accessibility and transparency in European law, competent authorities are now better able to supervise the market and this further promotes consumer safety. The CosIng database contains more than 15,000\(^{454}\) cosmetics ingredients, and is accessible in a user-friendly manner. It also provides more information for labelling purposes such as chemical name of the ingredients and their international recognized name. This system contains all data since the introduction of the Cosmetics Directive in 1976.

### 3.4 Part III: Issues regarding the implementation of cosmetics safety legislation in the EU Member States

**Introduction**

In this part, the discussion is commenced with issues and debates surrounding the implementation of the Cosmetic Directive in the EU. As mentioned in the previous parts, the Directive sets the requirements of both the pre-market control, which has been seen as one of the main tools underpinning the EU cosmetic framework, as well as the post-marketing surveillance activities which are carried out for the purpose of monitoring the actions to verify the compliance with the underlying rules. This part moves further to analyze the issues and some discussions underneath the current

\(^{453}\)Ibid.

operation of cosmetic system. Among the issues discussed are the requirement to transpose the EU Directive into national legislations which often involve difficulties, such as in implementing pre-market activities, the handling of non-compliance cases, chemical compositions requirements and the information sharing on non-compliances cases. There is also a discussion on cosmetovigilance system in the EU which has been established due to problems of cosmetic related injuries that has heightened in the recent years. This part ends with the discussions on the new EU Cosmetics Regulation\textsuperscript{455} which was introduced in July 2009 and is replacing the EU Cosmetics Directive.

3.4.1 The application and implementation of the Directive in the Member States

3.4.1.1. Transposing the EU Cosmetics Directive into the national legislations

A difficulty in the implementation of the Directive was in transposing it into all the national legislations because of the different approaches, additional national legislation required, errors and, timing issues that are normally associated with this process. The main cosmetics association in Ireland, The Irish Cosmetics, Detergent and Allied Products Associations (ICDA) argued that such situations are ‘contrary to the principle of the free circulation of goods on the European Community market and adds to the uncertainty under which companies try to operate.’\textsuperscript{456} As mentioned previously, the responsibility for ensuring that cosmetics products comply with the requirements set out in the Directive lies with the manufacturer or the importer of the product. However, it is submitted that the Cosmetics Directive is not explicit about the role of the competent authorities in each of the member states, apart from a stated responsibility to ‘prohibit the marketing’ of products in breach of the Directive. Consequently there is scope for considerable variation between Member States in the approach taken towards the implementation of the Directive.\textsuperscript{457} Among the instances is the implementation of the pre-market surveillance carried out by the competent authorities to ensure that cosmetics products comply with the Directive, and how instances of non-compliance are dealt with. This is illustrated by the fact

\textsuperscript{455}EU Regulation 1223/2009.


\textsuperscript{457}DG Enterprise and Industry, \textit{supra}, p.33
that each time an ingredient is added to the text of the Directive (or removed) this must be transposed into national law in each of the 27 member states. This process is therefore very time-consuming for member states and causes delays that could affect consumer health.

### 3.4.1.2. Pre-market surveillance implementation

It was reported\(^\text{458}\) that pre-market surveillance is organised and resourced in different ways across the member states. The competent authority usually organises and conducts the pre-market surveillance of cosmetics products. If it does not have the technical expertise in-house then testing is contracted out to a suitable facility. However, the extra costs of this can prevent some competent authorities from fulfilling this requirement. For example, in some cases the Romanian authorities have been unable to conduct tests because no suitable laboratory facility has been found.\(^\text{459}\) In some countries, the surveillance of cosmetics products is delegated to regional or even local government, like the UK where its pre-market control is the responsibility of over 200 Trading Standards departments based within local government.\(^\text{460}\)

Sweden has adopted a similar, highly decentralised system of surveillance while it was reported that in some other countries,\(^\text{461}\) regional government carries out pre-market cosmetics surveillance. The resources committed to pre-market surveillance also are reported to vary between member states.\(^\text{462}\) The proportion of resources committed to the surveillance of cosmetics products relative to other activities is determined in part by the other responsibilities of the Competent Authority.

### 3.4.1.3. The handling of non-compliance cases (for PIF)

As explained in Part II, in terms of labelling and the chemical composition of products, the Cosmetics Directive is very clear about what constitutes non-compliance. However, there is no set template for the contents of PIF (as explained earlier) and consequently member states have no frame of reference against which

\(^{458}\) Ibid.

\(^{459}\) Ibid.


\(^{461}\) Bulgaria, Slovakia and Estonia, ibid.

\(^{462}\) Ibid.
to judge compliance. As noted above, report has mentioned\textsuperscript{463} that there is also considerable variation in the approaches taken by competent authorities towards assessing PIFs, making it hard to draw overall conclusions about non-compliance in this area. The Cosmetics Directive is also unclear about procedure in the event of product non-compliance. Ultimately, competent authorities are required to ensure that products that do not meet the requirements of the Directive are not put on the market, but in reality the approaches taken by member states vary depending on the nature and severity of the breach. Again, the issue is particularly complicated for the PIFs since there is no set definition as to what constitutes compliance.

3.4.1.4. Chemical Ingredients Requirements

The EC 2007 report mentioned earlier\textsuperscript{464} held that in non-compliance cases, the most common grounds is the presence of banned ingredients in products. The examples noted is the use of \textit{Hydroquinone} which has been reportedly found in skin lightening products in some countries.\textsuperscript{465} The earlier analysis of RAPEX data regarding cosmetics reveals that the discovery of a substance called \textit{Dibutyl Phthalate} in cosmetic products is the single most common cause of a RAPEX notification.\textsuperscript{466} Second, most frequent issues are cases where the concentration of ingredients has exceeded the permitted level as the case of \textit{Hydrogen peroxide} in dental whitening product mentioned earlier. Another example is the toothpaste containing \textit{Sodium Benzoate} at a level above that permitted for its use as a preservative found in Slovenia in 2004. There are also cases where cosmetics products were found to contain high levels of micro-organisms. For instance, \textit{Pseudomonas Aeruginosa} was discovered in cosmetics by the Slovakian authorities in 2004 and 2006.\textsuperscript{467}

Non-compliance with product chemical composition requirements as the examples above is arguably the most serious breach of the Cosmetics Directive in terms of the potential impact on consumer health, and consequently member states are relatively strict where products failed in market checks. Where a product was

\textsuperscript{463}\textit{Ibid.}
\textsuperscript{464}\textit{Ibid.}, p. 41.
\textsuperscript{465}Austria, Belgium, France and Slovakia are reported of such use. Other examples reported are a number of authorities have discovered cosmetics products containing the prohibited substance Dibutyl Phthalate (such as in Finland in 2006 in a nail polish, and also in France and Latvia). Banned Glucocorticoids have been found in products in France and Austria. \textit{Ibid.}, p. 42.
\textsuperscript{466}See the discussion on post-marketing surveillance, in part II previously.
found to be in violation of the Directive, the manufacturer or importer was almost always instructed to withdraw it from the marketplace immediately. This is one of the examples of the non-standardised practise between the member states. In many cases the authorities then seized and destroyed the offending products. In Belgium, for example, it was reported that a number of skin lightening products were removed from the marketplace and destroyed after they were found to contain the banned substance Hydroquinone.⁴⁶⁸ Depending on the nature of the offence and the level of cooperation from the offending cosmetic companies, cosmetic companies might also be fined or even taken to court such as has been reported as happening in Bulgaria, Slovakia, the Czech Republic and Belgium.⁴⁶⁹

3.4.1.5. Cosmetovigilance system
On 8 November 2009, the Council of Europe recommended in a resolution⁴⁷⁰ that the governments of the member states:

‘[i]mplement in their national policies a cosmetovigilance system with an involvement of competent authorities and stakeholders like health professionals, producers, consumers, and which embraces the Intergovernmental Information Network for Cosmetic Products (INCOS) for exchange of information between governments about serious undesirable effects caused by cosmetic products.’⁴⁷¹

Cosmetovigilance is the process through which the potentially harmful effects of chemical ingredients or cosmetics products are identified and researched. It is actually referred to as a term for post marketing surveillance system for cosmetic. Cosmetovigilance has been established due to problems of cosmetic related injuries that have heightened in the recent years. Several studies⁴⁷² have held that problems with use of cosmetic products can be linked to adverse cosmetic reactions/effects or

⁴⁶⁸Ibid., p. 43
⁴⁶⁹Ibid.
⁴⁷¹Ibid.
known by scientists as ACR/ACE. One of the studies involved a survey on cosmetovigilance in the EU where the aim of the survey was to consider the commonness and type of ACR/ACE reported by consumers and the following measures implemented and the result of the survey had been published in Journal of Pharmacological Research.

In the EU at present, there is no harmonised cosmetovigilance system at European level. The studies mentioned that post-marketing vigilance system for cosmetics is different from country to country, especially in regards to ACE/ACR notification. This points to the fact that although some countries have systems in place to gather reports, others do not. However, despite the non-harmonised cosmetovigilance scheme in the EU, in some Member States, there are some examples where cosmetovigilance has been incorporated into their health legislation. France for instance has set up an official cosmetovigilance system by publication of act N°. 2004-806 dated August 9, 2004, relating to public health policy. The new statutory provisions define the concept of a serious adverse effect and the reporting obligations for healthcare professionals and manufacturers. Another Member States that has such system is Sweden. It has a Cosmetovigilance Centre, founded in 1989 and run by the Department of Cosmetics. This national Swedish authority is responsible for collecting ACRs reported by different categories of bodies.

It seems that ongoing development of new ingredients, coupled with advances in understanding of the ways in which existing chemicals affect human health (particularly long-term effects), mean that cosmetovigilance is a continuous activity. However, the Cosmetics Directive does not include any specific requirements in respect of the process of cosmetovigilance, other than the manufacturers’ responsibility to ensure that products do not cause harm, and to maintain information in the PIFs regarding undesirable effects on human health resulting from

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473 Adverse Cosmetic Reactions (ACR), Adverse Cosmetic Effects (ACE)
475 However, in the EU Cosmetic Regulation which will be implemented in June 2013, there are specific provisions on cosmetovigilance. See further discussions in next section.
the use of the cosmetic product. Instead, the process is determined at the level of the Member State, potentially drawing on consumers, health professionals (doctors, dermatologists), businesses, the research community (universities, research centres), and government.

It is reiterated that the primary aim of a well-structured cosmetovigilance system is not only to examine but also to avoid the risk of adverse ACR/ACE through a collaboration and harmonization between scientific experts, cosmetic industry and consumer associations. This could certainly improve cosmetic safety of the EU. In 8 November, 2006 the Council of Europe’s Committee of Ministers (during the 979th meeting of the Ministers’ Deputies) has adopted a resolution called ‘Resolution ResAP (2006)1’ on a vigilance system for undesirable effects of cosmetic products in the EU to protect public health. The primary focus of the Resolution was the operation of the Directive in the field of consumer protection. The effectiveness of the Directive in this regard can be assessed, firstly, by whether cosmetovigilance systems work together with the Directive to identify dangerous ingredients and provide the necessary information from which to evaluate the risks to consumers.

Although the independence of the SCCP has been commended, the process through which ingredients are assessed was argued to be too slow. Furthermore, systems of cosmetovigilance were criticised for being too fragmented and unable to provide sufficient comparable, EU-wide information on the scale of the problem. A public consultation was held in regard to the revision of the current Cosmetics Directive. The Commission submitted for public consultation the question of whether the Directive should include a requirement for the Commission to assist in co-operations between the Member States in the field of cosmetovigilance. It is

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479 Article 7a of the EU Cosmetic Directive.
481 This resolution was adopted by the Committee of Ministers on 8 November 2006 at the 979th meeting of the Ministers’ Deputies. At https://wcd.coe.int/ViewDoc.jsp?id=1061283&Site=CM, (last accessed 12 June 2012).
482 Ibid.
484 Ibid.
486 DG Enterprise and Industry, 2007, p. 49.
submitted that all of the responses papers\(^{487}\) from the stakeholders\(^{488}\) agreed to such provision. The Cosmetic Toiletries and Perfumery Association\(^{489}\) (CTPA) for example, indicated that ‘it is necessary that the European Commission should co-ordinate any activities in this regard to prevent a plethora of different systems operating at national level so as to minimise the impact of the additional burden.’\(^{490}\)

3.4.2 The new EU Cosmetics Regulation\(^{491}\)(which is replacing the EU Cosmetics Directive)

As mentioned in the introduction, the EU is replacing the current Directive with a new Regulation. A stakeholder consultation was held, from 12 January 2007 to 16 March 2007 before the Regulation is introduced in which the European Commission received 72 responses to this consultation. The consultation showed that the Directive needed to be ‘recast’ both in its structure and in the content of specific provisions. Recasting is ‘a legislative technique which enables codification of a legislative text and its amendments and to introduce substantive improvements.’\(^{492}\) The consultation also emphasised that ‘in order to ensure a high level of protection of human health throughout the EU and to ensure an internal market for cosmetic product, a recast Cosmetics Directive should take the form of a Regulation.’\(^{493}\) Its introduction, its emphasis on product safety and the inclusion of room for technological developments (i.e. nanotechnology) signals the EU’s advanced and ambitious standards which make it the global leader. In contrast to the present arrangement where the Directive has had to be transposed into the national legislation of 27 countries, no transposition will occur with the Cosmetics Regulation,

\(^{487}\)There were 72 response papers altogether, however, 7 stakeholders requested confidential treatment of the submission. See http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm\#h2-the-new-cosmetic-products-regulation, (last accessed 7 January 2011).

\(^{488}\)Stakeholders consulted including the national authorities, the cosmetic industry and the consumer organisation.

\(^{489}\)The Cosmetic, Toiletry and Perfumery Association (CTPA) is the trade association that represents the cosmetics industry in the United Kingdom. It has over two hundred companies in membership covering approximately 85% of the UK cosmetics market by value. CTPA is a member association of COLIPA, the European Cosmetic, Toiletry and Perfumery Association, now known as Cosmetics Europe.

\(^{490}\)Ibid.

\(^{491}\)Regulation 1223/2009.


\(^{493}\)Ibid.
but will automatically be applied to all member states thus preventing member states from deviating from the official text in any way.

The EU commission has identified issues which need to be improved from the exercise in the existing Directive.\(^{494}\) First, there are legal uncertainties and inconsistencies as well as ‘burdensome management’ to the Cosmetics Directive. The inconsistencies have been confirmed by the many amendments which have led to various conflicting provisions and incoherent terminology. For example, the Directive contains no list of definitions, and despite many amendments, they have never been formally incorporated into a single legal text.\(^{495}\) Many terms need clarifications such as ‘person responsible for placing the cosmetic product on the market,’ ‘minimum durability,’ ‘undesirable effects,’ ‘rinse-off products.’\(^{496}\) The report also made clear that technical and scientific terms needed to be improved in the annexes.

Second, the current Directive is identified as bringing about considerable unnecessary costs for cosmetic industry. For example, to comply with the Directive, the industry must label the certain ingredients in the incomplete inventory into the national language. This is identified as causing considerable additional costs. Further unnecessary costs are found in the analytical methods that ensure compliance with substance restrictions.

Third, apart from the difficulties to the cosmetic industry, national competent authorities also felt the burdensome management caused by the directive. For example the ‘incompleteness of inventory which makes pre-market controls of products and their substances more burdensome and costly.’\(^{497}\) The authorities, in implementing pre-market control, also have to build up their own method of analysis. This is costly as it involves great technical expertise.

Fourth, the report assessment had identified that the existing Directive provides for ‘exhaustive harmonization’ of the national rules on labelling as well as packaging of cosmetics together with rules of substances used for consumer safety reasons. The member states may not implement additional rules in this area. A further complaint has been over the content and annexes of the Directive which in


\(^{495}\)However, a consolidated version (that is an informal text incorporating all of the amendments) was made available by the Office for Publication on 9 August 2006.

\(^{496}\)A summary of suggested items in the public consultation can be found in Annex 1.

many cases are too specific and are therefore too restrictive when Member States come to transpose them. However, the directive and the amendments are still required to be transposed by member states which lead to problems for EU businesses, as the national transpositions maybe different. Thus, based on the issues identified, it was held that the new Regulation is vital to avoid differences in national transposition which do not contribute to product safety, but instead add to the regulatory burden and administrative costs.

There are certain important changes with regards to the Regulation compared to the existing practise in the Directive. First, cosmetic product notification is being introduced.\textsuperscript{498} One of the most important changes in the new Cosmetics Regulation is the introduction of Cosmetic Products Notification Portal (CPNP).\textsuperscript{499} This requirement, specified in Article 13 of the Regulation places a mandatory obligation for all cosmetic products produced in the EU to be notified all member states. At the moment the Cosmetics Directive has no official notification requirements placed on the manufacturers.\textsuperscript{500} Another important change is the introduction of a formal cosmetovigilance system which has been added as a provision of the Regulation.\textsuperscript{501} It is stated in the Cosmetics Regulation that;

‘In the event of serious undesirable effects, the responsible person and distributors shall without delay notify the competent authority of the Member State where the serious undesirable effect occurred. In the event that the serious undesirable effects reported by the responsible person/distributors to the competent authority of the Member State where the effect occurred, that competent authority shall immediately transmit the information to the competent authorities of the other Member States.’\textsuperscript{502}

All of this will come into effect with the Regulation in July 2013.

Other the most significant changes in the new Regulation as compared to the existing Directive are the provisions on nanotechnology in cosmetic products.\textsuperscript{503}

\textsuperscript{498} The current Directive has the notification system but the provision only applies for imported cosmetics products to be placed on the EU market. See Section 7 a (4) of the EUCD.

\textsuperscript{499} Introduced in January 2011

\textsuperscript{500} See the comparison of the new EU Cosmetic Regulation’s notification system with Malaysia’s notification system in Part II of the comparative chapter.

\textsuperscript{501} Article 23 of the Cosmetic Regulation 1223/2009

\textsuperscript{502} Article 23 (3) and (4) of the Cosmetic Regulation

\textsuperscript{503} A specific discussion on nanotechnology in cosmetic is in chapter 7
only does it define such materials; it also requires them to be appropriately labelled on cosmetic products. Chatham House has published a Report\textsuperscript{504} saying that this change differs from other recent amendments to existing EU regulations, such as revisions in food regulation which has referred more generally to ‘nanotechnology’ and ‘changes due to particle size.’\textsuperscript{505} The Regulation also includes new provisions that would toughen market surveillance and consumer labelling of nanomaterials in cosmetics.\textsuperscript{506}

Furthermore, the new Regulation has mandatory guidelines relating to safety assessments and reports for producers. The assessment is required to have information on the predictable systemic exposure to particular substances in the finished formulation. The safety report needs to remain updated even if more information comes to light after the product is in the marketplace.\textsuperscript{507} When the producer carries out the assessment, care must be taken to minimise ‘any possible impacts on exposure due to particle size.’ The responsible person\textsuperscript{508} has to create and update a product file, and should be made available to competent authorities if requested. The file should include a description of its manufacture and a product safety report. In addition to these obligations, the regulation specifies that prior to placing a cosmetic product on the market, the responsible person must notify the Commission of ‘the presence of substances in the form of nanomaterials.’\textsuperscript{509} This information must be accessible to Member States and national poison control centres for market surveillance.

### 3.5 Conclusion

In this chapter, the sphere of the EU Cosmetics Directive’s implementation was analysed. The pre-market control has been seen as the main tool underpinning the EU cosmetic framework, while the post-marketing surveillance activities are carried out with a view of monitoring the actions to verify the compliance with the underlying rules. This chapter further analysed the issues and some discussions


\textsuperscript{505} Ibid., p. 78.

\textsuperscript{506} Details provisions are in chapter 7.

\textsuperscript{507} Article 10, paragraph 1(a) and (c).

\textsuperscript{508} The term ‘responsible person’ as defined in Article 4 generally refers to the importer or manufacturer of a cosmetic product, European Commission, 2008h.

\textsuperscript{509} Article 13, Paragraph 1(f).
surrounding the current operation of the cosmetics system in the EU. It is noted that when a policy has been created, in this case the Cosmetics Directive, the Directive needs to be transposed into each member states’ national laws for implementation. Consequently, there exists non-standardised techniques, for example since the Directive is not explicit about the pre-market surveillance, member states have adopted very different approaches where some are more thorough than others. As the study of cosmetics related illness/problems is acknowledged, cosmetovigilance is yet another matter that is relevant to the discussions in the EU which is not addressed in the current Directive. However, the yet to be new implemented Cosmetics Regulation in the EU which has been explored in the last section of this chapter has revealed certain gaps in the current Directive, such as in the cosmetovigilance system. In fact the new Regulation, when fully implemented, will fill in many gaps in the current system especially where there is a divergence in practices of implementation in member states. This will no longer be an issue when it is fully implemented as no transposition will be necessary. The discussion then moved to the new recast technique which leads to the simplification of the laws, and there is also some new important elements included in the new regulation i.e. the provisions on nanotechnology. However nanotechnology is not thoroughly discussed in this section as it is analysed exclusively in its own chapter (chapter 7 in this thesis.) In short, extensive control is observed for cosmetics in the EU, which is evidenced by three elements of safety controls in its cosmetic safety legislation. First, there is European legislation that requires cosmetics to be safe, based on the control of the compositions to be used in cosmetics, where an independent scientific committee has given opinions or advice with regard to the ingredients. Second, there is the professional safety assessor who indicates that the cosmetic product is safe. Third, there is the control by authorities checking on products placed on the market.

It is admitted that there have been problems in terms of the lack of standardised implementation system especially in terms of transposing the law into each national legislation, and carrying out a surveillance system, (as previously addressed in Part II and III) which is very time-consuming for member states and causes delays that could affect consumer health. Although such issues can hopefully be eradicated by the implementation of the new Regulation, it is still unknown to what extent the regulation will be more efficient, although theoretically it will be
more efficient as it covers a number of gaps, as mentioned earlier. All these measures are mainly intended to ensure the safety of cosmetics placed on the market.
Chapter 4: The USA and Its Cosmetic Self-Regulatory Scheme

4.1 Introduction

Cosmetic regulation in the USA started very early. This is evident by the fact that USA has the oldest law regulating cosmetic in the world, namely the Federal Food Drug and Cosmetic Act 1938 (the FD&C Act). As the time passed by, cosmetic use in USA has expanded and its cosmetic industry is noted as one of the largest and among most profitable sectors of the economy worth reportedly approximately £35 billion\(^{510}\) per year and ‘spends more money on television advertising than any other business’s.’\(^{511}\) Cosmetic regulation in the USA is under the auspices of the Federal Drug Agency (FDA). The most significant difference from many other jurisdictions in respect of its cosmetic regulation is its self-regulation scheme.\(^{512}\) That means the FDA relies heavily on the cosmetic industry to regulate itself in order to ensure consumer safety. This is contrary to a popular belief that FDA has the power to test or determine the safety of cosmetics or have the ingredients reviewed and approved before they are released on the market.\(^{513}\) The Personal Care Products Council (PCPC)\(^{514}\) is the leading cosmetic trade association in the USA representing the personal care products industry and is known to play a major role in the USA cosmetic regulation. Founded in 1894, it has more than 600 member companies that manufacture, distribute, and supply the vast majority of finished personal care products marketed in the USA.\(^{515}\)

This chapter discusses how the safety of cosmetic is regulated in the USA, the background of the current law and the insights of the implementation of the self-regulatory scheme. It is divided into three parts. Part I deals with the history of the USA’s legislation of cosmetics which depicts the background of the underpinning law in the early stage, including the poignant stories of the unsafe cosmetics which resulted in the enactment of the law. Part II moves on to the current legislation i.e. on how the safety of cosmetic is determined, that is what tools are used to control

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\(^{510}\) G. Kay, 2005, p. 2.


\(^{512}\) Goldstein, D, ‘Dangerous Cosmetics,’ The Herald, Miami, FL (www.herald.com) March 29, 2005

\(^{513}\) Lindy Woodhead, War Paint: Madame Helena Rubinstein and Miss Elizabeth Arden: Their Lives, Their Names, Their Rivalry, 2003, p. 204.

\(^{514}\) Before 2007, it was formerly known as the Cosmetic, Toiletry and Fragrance Association or CFTA.

\(^{515}\) At http://www.ctfa.org/, (last visited 7 July 2012).
cosmetic safety. Here, the scope of law and the relevant agency’s jurisdiction are discussed. Some brief comments on drugs regulation however are made in order to permit an insight into the perspective of how cosmetics safety regulation is approached especially in regards to how cosmetics are different from drugs. Also, as post-marketing surveillance plays a significant part in the safety mechanisms, it will also be analysed in light of the FDA’s jurisdiction such as conducting inspection, issuing warning letters and recall. Lastly, Part III deals with the analysis of the recent critics over the cosmetic’s self-regulation in the USA. A consumer watchdog agency, the Environmental Working Group (EWG) for example, is among the most notable consumer groups that strongly criticize such a regime claiming that it is ineffective and inadequate in terms of protecting the consumer safety. As, there are also many academic papers suggesting that the current self-regulatory scheme for cosmetic is inadequate and that USA’s Federal Drug Administration (the FDA) requires more stringent standards, the basis of the criticisms is thoroughly discussed in this part.

4.2 Part I: The background of cosmetics legislation in the USA

4.2.1 History: The beginning of cosmetics in the USA

The development of cosmetic in the USA started as early as the 1800s. Similar to the EU counterpart, cosmetics were only worn by women and were mostly invented in private homes using home ingredients or ingredients bought from local pharmacies. During this period, it was socially unacceptable to wear visible make-up, as it was suggested that only prostitutes and actresses wore cosmetic at that time. Therefore, many women restricted their use of cosmetic to powders, fragrances and rouges. It was said that the recipes used to make the cosmetic sometimes contained hazardous ingredients such as lead, mercury, copper, tin, arsenic and bismuth. In some cases, women used these ingredients although there were warnings about the potential health hazards presented in such ingredients. In 1897, the subject matter of cosmetics safety was brought up in Congress when the Food and Drug Act was enacted. However, it was dropped from the draft because of the not

517 G. Kay, supra, 2005, p. 10.
518 Ibid.
519 Ibid., p. 11
so very significant sales of such products. Then later, the Act of 1906 was enacted, nevertheless it applied to only cosmetics that could also be brought under the definition of drugs. It was suggested that cosmetic was dropped from the 1906 act due to political decision as it was stated that ‘[i]n 1906 industry was considered so inconsequential that its inclusion would have been lowered the tone of legislation. Also, the beauty industry affected only women, and women could not vote.’ At that time, drugs included only ‘medicine and preparation ... and any substances or mixture of substances intended to be used for the cure, mitigation, and prevention of diseases.’ It was noted that the sale of cosmetic in the USA at that time were minimal and that the omission in the 1906 act did not appear to have an impact, or negative health repercussions, the way food and drugs had.

4.2.2 The ‘Cosmetics Tragedy’

In the early 1900s, the cosmetics industry sales were $100,000 but later expanded and in the 1920s, cosmetics sales were estimated at about $125,000,000 per year and about $150,000,000 in 1940. 1932 evidenced a number of revision proposals to the 1906 Act, which resulted from many tragedies involving unsafe cosmetics after commercialisation took off. One of the earliest accounts of a cosmetic hazard involved a special face cream called Koremlu, a depilatory cream which contained ‘thallium acetate,’ a poison that can cause selective forms of paralysis in customers using products containing one percent (1%) of thallium. The American Medical Association’s Bureau of Investigation found that Koremlu cream contained an ingredient that could poison the nervous system. Despite these health hazards, Koremlu cream remained available on the market, the only sources of warning to consumers were the press or word of mouth. As a result of many of unfortunate

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521Ibid., p. 13.
523Ibid., p.6.
524Ibid.
526Ibid., p. 13.
incidents involving cosmetics, the FDA prepared Tugwell Bill, an amendment to the 1906 Act that would have given FDA jurisdiction over the beauty industry. Despite being successfully promoted, the Bill however was not passed. This was due to the massive lobby by the cosmetic industry against the Bill. They argued that ‘factory inspection would reveal trade secrets and ingredient names would only confuse women.’ When Congress reconvened in the fall of 1933, the Bill was resubmitted. Out of eighty-four people that testified or submitted briefs at the hearing of the Bill, only seventeen people/institutions explicitly supported it.

Some tragedies continued to occur; among the most remembered ones is the Lash Lure case. It was a case where a woman went to her local beauty shop to ‘get done,’ touched up her eyebrows and eyelashes trying a popular eyelash dye called Lash Lure after it being recommended by the saloon. Almost immediately, her eyes itched and burned. A newspaper, The New Republic described her terrible condition the morning after as ‘her eyes are gone and the flesh around them is a mass of tortured scars.’ As a result, she lost vision in both eyes, and it is suggested that such a case was not the first case of ‘Lash Lure’ ill effects.

On the initiative of Senator Copeland, the improved version of the 1906 Bill was resubmitted in 1934, 1935, and 1936 but none was successful. In 1937, the Bill was finally reported out and various amendments were added that strengthened it including on the seizure provisions and ceded little advertising control to the FDA. On May 5, 1938, Copeland’s Bill was finally passed without debate and cosmetics were officially included. As with most laws, the Food Drug and Cosmetic Act did not come into effect immediately. Instead the law only took full effect on July 1, 1939 after a year of discussions regarding how to implement and enforce it. The reason for the delay was because of the provision of coal tar dyes used in eyelash and eyebrow dyes. The new law required cosmetics with coal tar dyes to add specific warnings on their label. As such, products, in particular the Lash Lure one described earlier, had

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527 It was called Tugwell Bill owing to the name of the assistant secretary of agriculture who began examining problems and loopholes in the 1906 Act. He sought the Congress to include cosmetic and therapeutic devices in the 1906 Act.
528 Mary Lisa Gavenas, 2002, p. 60.
529 Senate Bill 1944 (S 1944) by Senator Copeland.
531 Ibid., p. 1.
532 Ibid., p. 1.
533 Senator Copeland was a newly re-elected Senator who drafted another food and drug bill. In January 1935, Copeland introduced his new reform measure, S. 5, into the Senate.
caused problems and gone unchallenged. The FDA wanted to quash the problem immediately. Despite the fact that the law had been passed to include cosmetics, it was still claimed that the law was not perfect.\footnote{534} 

### 4.2.3 History of the cosmetics industry self regulation

The FDA has depended on the cosmetics industry to regulate the safety of cosmetics. This has brought about the self-regulatory regime for the cosmetics industry. During the early years of the implementation of the 1938 Act, there was already a great deal of cooperation between the FDA and the cosmetics industry. It has been addressed by the Chief of FDA at the time that '[C]ongress had not provided us with facilities nor the personnel to make clinical tests of drugs, cosmetics ourselves...We are dependent upon the reports of 'your' experiences,' the 'your' referring to the cosmetic industry.\footnote{535} There are two main incentives for the cosmetics industry in self-regulation; first, to ensure the industry image which involves the maintenance of favourable consumer perception about safety of the products so that they will continue to buy. Second, it is to ensure the industry's independence, as it was mentioned that '[p]art of the incentive for such industry policy is to avoid increased regulatory authority.'\footnote{536}

It was claimed that the FDA dependency on the industry collaboration has not only been useful but also crucial due to the budgetary limitations particularly in terms of resources and personnel. It was also suggested that regulation on cosmetics did not necessarily require a more stringent regulation since cosmetics were generally safer than other product regulated under the FDA's jurisdiction, and thus the FDA should not be hampered given its other high priorities. For example, the Cosmetic, Toiletry and Fragrance Association or CFTA President at the time highlighted that '[T]he last thing this country needs is more unnecessary government regulation. Let’s talk about today’s realities and pressing priorities. Let’s not ask FDA to spend more on a problem that doesn’t exist at the expense of real crisis- AIDS, Alzheimer’s, new drug approval, food safety.'\footnote{537} This also reflects the restricted jurisdiction of the FDA that it only regulates cosmetics after they are released on the market, not prior. It has been has claimed that '[i]n regulating cosmetic, the functions

\footnote{534}{This was said by Dr. Walter Campbell, the Chief FDA at the time.}
\footnote{535}{G. Kay, 2005, note 11, pp. 119–120.}
\footnote{536}{Judith E. Foulke, ‘Cosmetic Ingredients: Understanding the Puffery’, FDA Consumer, May 1992.}
\footnote{537}{Ed Kavanaugh, ‘No Need to Tighten Cosmetic Safety,’ \textit{USA Today}, April 12, 1990, at 10A.
of the agency is like a highway patrolman...FDA regulation of cosmetics is entirely ex post.”

As a result of the self-regulatory scheme, cosmetics in USA are neither required to undergo any product registration nor any pre-market approval process. As such, Hutt expla ines that it was not the intention of the Congress at that time to require ‘pre-market testing, pre-market notification, pre-market approval, or any other form of listing or registration’ of cosmetic in the 1938 Act.

However, one of the important components as a result of the refusal by the FDA to require pre-market scheme for safety assessment of cosmetic ingredients is the establishment of the Cosmetic Ingredient Review (CIR) which was established in 1976 by the CFTA (the former PCPC). Although financed by the cosmetic industry, CIR is an independent organization which has independent scientists and is tasked with reviewing the safety process without any bias to the industry itself as it claims, ‘[t]he CIR thoroughly reviews and accesses the safety of ingredients used in cosmetics in an open, unbiased and expert manner, and publishes the results in the open, peer-reviewed scientific literature.’

Without the statutory authority for pre-market approval, another programme was also developed by the FDA with the cooperation with cosmetic industry; called Voluntary Cosmetic Registration Program or VCRP. Under this, cosmetic manufacturers are encouraged to register their cosmetic business with the FDA with a view to informing it of their existence and location. The entire mentioned programs however, are only voluntary without any mandatory effect. Until today, this scheme is still in practice and remains essentially unchanged.

### 4.3 Part II: How is the safety of cosmetics ensured in the USA?

#### Introduction

This part examines the law that regulates cosmetics safety and other supporting laws and mechanisms as well as the post-marketing tools used to complement the safety system of cosmetics in the USA. The 1938 Act does not give authority for the FDA to

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539 Peter Barton Hutt, op.cit, p.38

540 Ibid., p. 7.


542 21 CFR § 710.
mandate cosmetic registration, ingredient listing compliance, or pre-market data submission or safety authentication for cosmetic products which are going to be marketed. This approach has been considered by some critics as too lenient or not a stringent enough way to regulate the safety of cosmetics. Comparing cosmetics with other products under the FDA’s purview, it has been highlighted by Greff\textsuperscript{543} that requirements for cosmetics are considerably less extensive and complex than requirements for foods, drugs, or medical devices.\textsuperscript{544} The agency however, has been supported by other legislative mechanisms in order to provide better protection to consumers with safer cosmetics. One of the mechanisms is the regulation of colour additives, which has been in the place since 1960.\textsuperscript{545} Another instrument imposed by the law is the requirement for safety labelling and the manufacturer’s duty to warn which is obligatory for the cosmetic products whose safety are not substantiated or tested. Apart from the above mechanisms, post-marketing activities have been recognised as important tools. Here, the surveillance and monitoring control involves inspection by the agency, issuing warning letters and recall. The programme mentioned earlier, the Voluntary Cosmetic Registration Program (VCRP), is also part of post marketing activities administered by the FDA.

4.3.1 Cosmetics regulations and other supporting safety mechanisms in the USA

4.3.1.1. The Federal Food Drug and Cosmetic Act 1938

The safety of cosmetics in the USA is ensured by the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act). According to the FD&C Act, cosmetics are defined as:\textsuperscript{546}

‘articles 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, and article intended for use as a component of any of such articles; except that such term shall not include soap.’

\textsuperscript{543}A. Greff, \textit{supra} note 6, p. 248.
\textsuperscript{544}\textit{Ibid}.
\textsuperscript{546}\textit{FDC&A Section 201 (i).}
According to the definition, cosmetics in the USA can be classified into several categories which include traditional make-up, skincare products, perfumes and fragrances, as well as hair care products. Examples of cleansing products included under the cosmetics category are facial cleansers, mouthwashes, make-up removers, also shower foam/bath and shampoo. Since the definition also covers products used for 'beautifying, promoting attractiveness or altering the appearance,' hair dyes, tanning products and manicure products such as nail colouring products also fall under the cosmetics category. Other examples of products are deodorants, shaving products and baby products. In short, it can be deduced that a cosmetic is a product intended to exert a physical, and not a physiological, effect on the human body.547

a) Adulterated and misbranded provisions under the FD&CA

One of most important elements in the FD&C Act in terms of safety provisions concerning cosmetic products is that the law forbids the marketing of ‘adulterated’ or ‘misbranded’ cosmetics in interstate commerce. Adulterated cosmetics refer to violations of the Act involving product composition, or whether they result from ingredients, contaminants, processing, packaging, or shipping and handling and therefore are subject to regulatory action.548 A cosmetic is ‘adulterated’ under the Act if: 549

- it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labelling thereof, or under conditions of use as are customary and usual [with an exception made for hair dyes];
- it consists in whole or in part of any filthy putrid, or decomposed substance;
- it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

548Issuance of warning letter, request to recall products, civil seizure action, injunction action or a criminal proceeding. Further discussion is in the next section.
549FD&C Act, sec. 601.
its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; [or except for hair dyes,] it is, or it bears or contains, a colour additive which is unsafe within the meaning of section 721(a).

The above provision specifies that a cosmetic or its substances must not contain any potentially hazardous substances when used under the prescribed conditions or label. The condition also extends to the whole preparation of cosmetics when prepared and packaged in a container and outer packaging. While the violation with regards to illegal compositions can specify cosmetics as being adulterated, improperly labelled or deceptively packaged products are considered ‘misbranded’ and are also subject to regulatory action.\textsuperscript{550} Under the FD&C Act, a cosmetic is considered ‘misbranded’ if:\textsuperscript{551}

its labelling is false or misleading in any particular;
its label does not include all required information;
the required information is not adequately prominent and conspicuous;
its container is so made, formed, or filled as to be misleading;
it is a color additive, other than a hair dye, that does not conform to applicable regulations issued under section 721 of the FD&C Act; and
its packaging or labelling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

With regards to the adulterated and misbranded provisions, it seems that such provisions raised issues as to whether they can be regarded as an implied general safety provision or not. Some academics\textsuperscript{552} have taken the view that such provisions have a \textit{de facto} effect, in that it is an implied obligation for the cosmetics manufacturer to produce only safe cosmetics. However, there are many others who have stated that these provisions do no such thing. In addition, the provisions are not without their critics – it has been said that they have produced little litigation.\textsuperscript{553}
b) Differences of drugs, over the counter drugs and cosmetics

Having understood the definition of cosmetics in the regulation, it is also important to understand the extent to which cosmetics are regulated according to the law. Based on the definition, a common issue in cosmetics regulation in the USA and in many other markets is the distinction made between cosmetics and drugs. The reason for this is that cosmetics are sometimes treated as drugs or vice versa. In fact, although the cosmetic-drug distinction is a global problem, in the USA particularly, this issue seems to be much debated. In fact, the misbranding cases that have arisen have primarily addressed the issue of cosmetic/drug distinctions.

In the USA, the Drug Amendments of 1962 strengthen the new provisions for drugs in the 1938 Act rendering a very important distinction between cosmetics and drugs. The complexity in the cosmetic-drug distinctions were heightened by the emergence of many new skin care products that were more complex and technologically advanced in the 1980s. As explained previously, in the USA and most jurisdictions, drugs, as opposed to cosmetics, need to undergo prior approval before they can be marketed.

In the USA, what constitutes a cosmetic and what constitutes a drug is defined by the intended use of the finished product. The reason for this is because a number of different laws apply to specific products. The ‘intended use’ of a product, as defined by the FD&C Act, can be surmised from its labelling. Some producers break the law by ascribing a drug claim to a cosmetic or by marketing a drug as a cosmetic. With this latter infringement they are attempting to circumvent the much stricter requirements on drugs. There are some products that meet the criteria to be both – and this possibility surfaces in products with two intended uses.

Apart from that, another significant element that exists in the USA product category is the over-the-counter drug (OTC). An OTC drug product ‘is a drug product marketed for use by the consumer without the intervention of a health care professional in order to obtain the product.’ These are categorised between

\[554\text{ Also happens in the EU, explained in Part II, Ch. 3.}\]
\[555\text{http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm, (last accessed 10 April 2012)}\]
\[556\text{Peter Barton Hutt, supra, 2000, p. 19}\]
\[557\text{Senate Report No 493, 73 d, Congress 2d Session, 1934.}\]
\[558\text{As explained in the FDA website accessible at http://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069917.htm (5 April 2012)}\]
cosmetics and drug and can be sold without prescription. Again, a product is considered a cosmetic or an OTC depending on its intended use and is based on the claims or on consumer perception. Examples of OTC are topical acne treatments, anti-caries and anti-plaque toothpastes, anti-dandruff products, anti-perspirants, skin lighteners, products for the protection of chapped skin or mucous membranes, sunscreens (including all products claiming a sun protection factor, even if this is not its main purpose). For all these products, the FDA has published OTC monographs, which are regulatory instruments for each specific category of OTC products.

According to the FD&C Act, prior to their release on the market, all new drugs must get a licence under the New Drug Application (NDA). However, drugs that are generally recognised as safe and effective (known as GRASE) are exempted. Since there were already many OTC drugs on the market before the requirements of the NDA had been mandated, the OTC monograph system was established. The OTC monographs are a sort of ‘recipe book’ according to the FDA that covers acceptable ingredients, formulations, and labelling which is regularly updated. Products that comply with the monographs may be marketed without prior approval from the FDA while those that do not, are required to be approved under the New Drug Approval System.

In short, unlike drugs or the OTC, cosmetics in the USA are not subject to pre-approval processes prior to being placed on the market. Although the FDA is limited to only monitoring cosmetic products that are already in the market, it does provide industry manufacturers, distributors and packagers with recommended guidance and a manual to assist people within the industry to develop a system that reduces the probability of selling adulterated and/or misbranded cosmetics.

c) Prohibited and restricted ingredients

The FD&CA also restrict or prohibit the use of the following ingredients in cosmetics: bithionol, mercury compounds, vinyl chloride, halogenated salicylanilides, zirconium complexes in aerosol cosmetics, chloroform, methylene chloride, chlorofluorocarbon propellants and hexachlorophene. These substances are prohibited or restricted because they are proven to be dangerous which can be a hazard to consumers’

559 http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm (12 June 2012)
560 21 CFR, Parts 250.2501 and 700.11 through 700.35
An example of this was during a period in the 1970s when many reports were made to the FDA about fingernail extenders that contained methyl methacrylate monomer. The result of its investigation into the injuries was that liquid methyl methacrylate was poisonous and should no longer be used in this way. Court proceedings followed and resulted in products with 100 percent liquid methyl methacrylate monomer being removed. Seizures, voluntary recalls and a preliminary injunction against a particular company followed the decision by the court. While these bans of mentioned substances have been due to the scientific evidence of their danger, it has been claims many times that such bans are not adequate, given that there are many more dangerous substances which are not banned in the USA but are banned in other countries, such as in the EU. The Campaign for Safe Cosmetics, a watchdog consumer agency has listed reports by many consumer groups which urge the FDA to consider banning more hazardous ingredients, as banned in other countries while other consumer websites such as Personal Care Truth, Healthy Tomorrow and Consumer Report Online have lobbied for the European-style chemical regulations which are stricter and have banned many more dangerous substances from being used in cosmetic formulations. Despite such efforts however, the number of banned substances remains fairly stable.

4.3.1.2. The Color Additive Amendment 1960

In the USA, a colour additive, as defined by regulation is ‘any dye, pigment, or other substance that can impart colour to a food, drug, or cosmetic or to the human

561 The potential hazard from these substances are explained in the FDA website at http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm127406.htm, (last accessed 20 June 2012).
562 At http://www.fda.gov/Cosmetics/ResourcesForYou/Consumers/CosmeticsQA/ucm167234.htm, (last accessed 10 June 2012).
563 As mentioned on the EU chapter, the EU has 1328 substances to the present day. See more discussions in the comparative chapter (chapter 6)
564 At http://www.safecosmetics.org/search.php?section_logic_plus=By+Section&class=By+Class&date=DateTime%3A&region=By+Region&q=&section=&template_section=&author=By+Author&tag=By+Tag&fulltext=ban+of+cosmetic&First_Name_2012=&AMPSearch=Search (last visited 10 July 2012)
565 At http://personalcaretruth.com/2011/05/the-eu-has-banned-1342-cosmetic-ingredients/ (last visited 10 July 2012)
566 At http://www.healthytomorrow.org/attachments/Cosmetics_FactSheet.PDF (last visited 10 July 2012)
567 At http://www.consumerreports.org/cro/index.htm (last visited 10 July 2012)
Colour additives are important components of many products, making them attractive and more appealing. Many cosmetic products are coloured. Lipstick and eye-shadow, for example, are among cosmetics which have many shades of colour. The more components used for coloured cosmetics therefore involve more complex procedures. Hence the number and complexity of the ingredients in colour requires greater scrutiny. In the USA, unlike the limited FDA regulation offered for the general cosmetics category, colour additives have been stringently regulated since 1960.

One of the FDA roles is to assure that colour additives are safely and appropriately used. The American congress thought that it was considered essential to have a comprehensive system requiring pre-market approval of all colouring substances used in foods, drugs and cosmetics.

Supervision of colour additives began at the federal level in the 1880s. Initially attention was directed towards evaluating colour-imparting ingredients in food. In 1881, the Bureau of Chemistry at the Department of Agriculture (USDA) began these examinations. The first foods using artificial colours, that met with federal government approval, were butter and cheese. By the turn of the century many more foods, as well as drugs and cosmetics containing artificial colours had been passed and were available to American consumers. However, it became apparent that sometimes colours were disguising inferior and defective food. An assessment of chemicals used in these foods also showed that many were harmful, for example, mercury, lead and arsenic. 1906 saw Congress pass the Food and Drugs Act banning harmful colouring agents in confectionery and the practice of colouring food to hide its deficiencies. The USDA was initially in charge of enforcing the Act, this then passed to the newly-created FDA in 1927.

By the 1930s it had become obvious that the Food and Drugs Act of 1906 was not robust enough to ensure the public was safe from misbranded, adulterated, and toxic consumer products such as the Lash Lure case mentioned earlier. The 1938

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569 Section 201(t) of the FD&CA and 21 CFR 70.3 (f)
572 The agency was first called the Food, Drug, and Insecticide Administration and was given its current name in 1930.
573 The Lash Lure case mentioned in part I.
Federal Food, Drug and Cosmetic Act tightened regulation on food and drugs and, for the first time, included regulation on cosmetics and medical devices. This Act required a mandatory list of coal-tar colours (other than coal-tar hair dyes) whose use was considered 'harmless and suitable' in all three categories.

Colour additive lakes were already being used and were included in the new Act. The first listing of lakes for use in food restricted them to colouring shell eggs. In response to the new Act, the FDA created the following abbreviations to denote certified colour additives: FD&C, D&C, and Ext. D&C. The FDA also brought in requirements for labels, adequate recording of information, specified technical improvements regarding colour additives and procedures for their certification.574

In the fall of 1950, due to the effect of eating an orange Halloween candy containing 1-2% FD&C Orange No. 1, a colour additive approved for use in food, many children became ill. That same year, U.S. House Representative James Delaney began holding hearings on the possible carcinogenicity of pesticide residues and food additives. These events prompted the FDA to reassess all of the listed colour additives. In the next few years, FDA found that several caused serious adverse effects and proceeded to terminate their listings. During that time, it also became clear that coal was no longer the primary raw material source for the manufacture of colour additives. The Color Additive Amendments of 1960 defined ‘colour additive’ and required that only colour additives (except coal-tar hair dyes) listed as ‘suitable and safe’ could be used in foods, drugs, cosmetics, and medical devices. The 1960 Amendments set down the factors that the FDA must consider in determining whether a proposed use of a colour additive is safe, as well as the specific conditions for safe use that must be included in the listing regulation. FDA updated the procedural regulations for the petition process in response to these amendments. Under these amendments, the approximately 200 colour additives that were in commercial use at the time were provisionally listed and could be used on an interim basis until they were either permanently listed or terminated due to safety concerns or lack of commercial interest. Permanently listing a colour additive for a proposed use was prohibited unless scientific data established its safety.

The 1960 Amendments also contained a ‘Delaney Clause’ that prohibited the listing of a colour additive shown to be a carcinogen. The clause states that ‘[a] colour

additive shall be deemed unsafe ... if the additive is found ... to induce cancer when ingested by man or animal, or ... after other relevant exposure of man or animal to such additive.’ After 1960, FDA gradually removed colour additives from the provisional list either by permanent listing or by termination of listing. Today about half of the ‘1960’ colour additives remain on the list; only colour additive lakes remain provisionally listed. However it was suggested that there are initiatives to permanently list them.

4.3.1.3. Cosmetic Labelling in the USA

The theoretical chapter discussed\(^{575}\) that proper labelling is another important aspect to consider before a cosmetic product is released on the market. It is also part of the cosmetic framework to promote safety. Lewis\(^{576}\) for example highlighted that the listing of cosmetic ingredient on the packaging is the only place ‘where a consumer can readily find out the truth about the cosmetic products she/he is buying.’\(^{577}\) Such an obligation is also a condition that has been imposed and implemented under the USA’s regulation of cosmetics. The FDA regulates cosmetic labelling under the authority of both the FD&C Act and the Fair Packaging and Labelling Act of 1973 (FPLA)\(^{578}\) as it applies to cosmetics. The laws require cosmetic manufacturers to declare the ingredients used in cosmetics by labelling them on all products that are intended to be sold to consumers. The FPLA specifies that the labelling provision is to ensure that packages and their labels supply consumers with correct information about the quality of contents and facilitate value comparisons.\(^{579}\)

Thus, these laws are particularly intended to protect consumers from health hazards and misleading practices and also to assist them to make informed decisions concerning product purchase. Responsibility for correct labelling requirements are given to the manufacturers. Cosmetic products that are improperly labelled or deceptively packaged or fail to follow with labelling requirements may result in a ‘misbranded’ product. Consequently, as discussed earlier, it is prohibited to introduce a misbranded cosmetic into interstate commerce, and such products are subject to regulatory action (see next discussions).

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\(^{575}\)Part II of theoretical chapter.


\(^{577}\)Ibid.


\(^{579}\)Ibid.
Another important aspect of the provision of false or misleading information is that no cosmetic may be labelled or giving suggestion statements signifying that ‘the FDA has approved the product.’ This applies even if the firm is registered with the FDA's Voluntary Cosmetic Registration Program (VCRP).\textsuperscript{580} It must be remembered that; false or misleading statements on labelling also make a cosmetic misbranded.\textsuperscript{581}

The FDA relies on the FPLA 1966 to require cosmetics manufacturers to declare the ingredients used in their products.\textsuperscript{582} The rationale for such a declaration and ingredient listing is to facilitate the consumers to make informed purchases by providing them with information about the contents of their products. O’Reilly for example suggested that such disclosure ‘[a]ids the consumer selection by decreasing the chance that a consumer allergic to an ingredient would knowingly purchase a cosmetic which contained that ingredient.’\textsuperscript{583} Under the requirements, all labelling information that is required by law must be in English. The exception here is if the product in question is aimed at an American territory where another language is predominant, for example Puerto Rico. If a foreign language is used, all required information under the FD&C Act must appear in the same.\textsuperscript{584} On the principal display panel\textsuperscript{585} the necessary information includes: an identity statement describing what the product is and its use by means of the common/usual name, a descriptive name, a fanciful name, or an illustration,\textsuperscript{586} and a statement giving the quantity of the contents (weight, measure, numerical count or a combination of these).\textsuperscript{587} The following information must appear on the information panel:\textsuperscript{588} company name and address,\textsuperscript{589} distributor information,\textsuperscript{590} material facts,\textsuperscript{591} and any warnings/cautions.\textsuperscript{592}

\textsuperscript{580}See 21 CFR 710.8 and 720.9, which prohibit the use of participation in the VCRP to suggest official approval.
\textsuperscript{582}Designation of Ingredients, 21 C.F.R. § 701.3 (1974).
\textsuperscript{584}21 CFR 701.2(b).
\textsuperscript{585}Principal display panel is the part of the label most likely displayed or examined under customary conditions of display for sale. See 21 CFR 701.10.
\textsuperscript{586}21 CFR 701.11.
\textsuperscript{587}21 CFR 701.13.
\textsuperscript{588}Information panel generally refers to a panel other than the principal display panel that can accommodate label information where the consumer is likely to see it. Since the information must be prominent and conspicuous, the bottom of the package is generally not acceptable for placement of required information, such as the ingredient declaration.\textsuperscript{--see 21CFR 701.2(a)(2)}
\textsuperscript{589}This may be the manufacturer, packer, or distributor. 21 CFR 701.12.
Also, cosmetics that may be dangerous to consumers must bear proper label warnings and the ingredients. An example of such harmful products is flammable cosmetics. However, it must be noted that there is a rare exception to the listing ingredients, which is applied in the case of trade secret. According to the FDC&A, a trade secret is described as ‘[a]ny formula, pattern, device or compilation of information which is used in one’s business and which gives one an opportunity to obtain an advantage over competitors which do not know or use it.’ Here, when a company is able to prove that certain cosmetic components are not well known by its competitors and qualify as a trade secret, the company needs only list ‘and other ingredients’ rather than including the specific ingredients that make up the trade secret.

4.3.1.4. The responsibility for substantiating the safety of cosmetics and duty to warn

In the USA’s cosmetic safety scheme, producers are obliged to verify the safety of their products before they are marketed. This obligation has resulted from the adulterated and misbranded provisions. Although it can be argued that the adulterated and misbranded provisions much broader and are not specifically aimed at ensuring the manufacturers’ responsibility to produce safe cosmetics. As mentioned earlier, these implied provisions can be said to be an incentive for the manufacturer to produce safe cosmetics, because, failure to verify their safety may mean that the products are misbranded. The law also specifies that cosmetic products that have not been ‘safety tested’ must include a warning that must appear conspicuously on the principal display panel of the product’s label. The

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590 If the name and address are not those of the manufacturer, the label must say “Manufactured for...” or “Distributed by...” 21 CFR 701.12.
591 Failure to reveal material facts is one of form of misleading labelling and therefore makes a product misbranded [21 CFR 1.21]. An example is directions for safe use, if a product could be used unsafe if used incorrectly.
592 These must be prominent and conspicuous. The FD&C Act and related regulations specify warning and caution statements related to specific products 21 CFR part 700.
593 21 CFR 740.1.
594 If the product is soled on a retail basis to consumers, even it is labelled ‘for professional use only’ or words to that effect, the ingredients must appear on an information panel, in descending order or predominance [21 CFR 701.3]. If the product is also a drug, its labelling must comply with the regulations for both OTC drug and cosmetic ingredient labelling.
596 21 CFR 701.3; 720.8 (2007).
597 21 CFR 740.10 (2007)
warning should be written as; 598 ‘Warning - The safety of this product has not been determined.’

Except for colour additives and those ingredients which need approval for use in cosmetics by regulation, a manufacturer may use any chemical component in the cosmetic formulation as long as the substance and the finished cosmetic are safe, the product is properly labelled, and the use of the substance does not otherwise cause the cosmetic to be adulterated or misbranded under the FDC&A provisions.

In 1975, the Cosmetic Product Ingredient Label Program was developed599 and was aimed at increasing consumer safety. The purpose of this programme is to assist in offering adequate substantiation of each ingredient listed on the product to prove their safety.600 Unsubstantiated products continue to require warning labels identifying the products as not having been tested for safety. The FDA has also developed a Cosmetic Labelling Manual 1991 with a view to educating the industry on labelling requirements to assist in self-regulated compliance.601

In the interest of educating manufacturers to ensure that labelling is not false or misleading, the FDA has drafted guidance documents on industry labelling for all cosmetic products containing alpha hydroxyl (AHA) ingredients.602 The guidance was developed following an increase in the number of adverse dermatologic experience reports between 1989 and 2000. Testing conducted as a result of these reports found that the AHA caused increased skin sensitivity to UV radiation, thereby increasing a product user's chance of becoming sunburned. The FDA's recommended labelling statement provides a reminder to consumers about product safety information.

As regards to the duty of warn by the manufacturers, despite the fact that warning is required for cosmetic products that have not been substantiated their safety, critics have been made that the provision does not make the safety testing of cosmetic by manufacturers mandatory before placing them on the market. The critics

598 21 CFR 740.10. Safety labelling and duty to warn is further discussed in part III of this chapter
601 See CFSAN, supra 51.
stressed that this provision is insufficient. According to Page and Blackburn,\textsuperscript{603} they held that the flaw of the warning lies in the language used. Instead of warning about the potential harm the products can bring without any testing assessment, the warning merely advises consumers that ‘products have not been safety tested.’ As many consumers in the USA mistakenly believe that the FDA tests the safety of cosmetics, Page and Blackburn have concluded that ‘[a]rguably, consumers would be better protected if they were simply made aware that most cosmetic are not tested for safety.’ Also, they added that based on the FDA’s prior enforcement record, the cosmetics industry will probably not adhere to the warning requirement and the FDA will not enforce it.\textsuperscript{604}

4.3.2 Post-marketing Surveillance activities

In addition to all of the elements mentioned, post market surveillance is conducted for ensuring the safety of cosmetics available to consumers. This section will examine what these activities comprise of in the USA cosmetic system.

i) Inspection

Without authority for pre-market control, the FD&C Act however authorises the FDA to carry out inspections of cosmetics firms at ‘reasonable times, in a reasonable manner, and without prior notice in order to assure adherence to the applicable laws and regulations.’ The purpose of inspection is to determine whether cosmetics are safe and labelled, and to identify possible health risks and other violations of the law.\textsuperscript{605} The purpose of cosmetics inspections is to assure their safety and determine whether cosmetics are adulterated or misbranded.\textsuperscript{606} Apart from the law, there are other guidance documents that provide additional information on the inspection of cosmetics; the Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist, Cosmetics Compliance Program and the Import and Domestic Regulatory Procedures Manual. There are a number of factors that affect how the FDA determines that an inspection of a cosmetic operation may be necessary. These include complaints from the public or other businesses, the company's prior behaviour in relation to

\begin{footnotesize}
\begin{itemize}
\item\textsuperscript{604}Page and Blackburn,\textit{op.cit.}
\item\textsuperscript{605}Section 704.
\item\textsuperscript{606}As defined in section 601 and 602 of the FD&C Act.
\end{itemize}
\end{footnotesize}
compliance, the FDA’s own investigations and its own ability to carry out the inspection.

Concerning inspection procedure, the FDA investigator must present identification and a written notice of inspection to the most responsible individual present before beginning the inspection. There are certain elements that should be observed by the investigator; use of prohibited ingredients, the use of restricted ingredients, non-compliance with colour additives requirements, microbial contamination, or failure to comply the requirements for tamper-resistant packaging where needed, incomplete labelling and packaging, the sufficiency of buildings and facilities, the suitability of equipment and how it is maintained, personnel training, handling of raw materials, production procedures, laboratory and other quality controls, warehousing and storage of raw materials as well as in-process and finished cosmetic, and complaint files.

If adulteration or misbranding is suspected or believed to happen, or as a follow-up to a cosmetic-related complaint or adverse reaction, an investigator is allowed to collect samples of cosmetics ingredients or finished products as part of scheduled surveillance. He can also collect products that are in-process, swabs from surfaces, and other relevant material to help determine if the suspicions are

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607 Section 704 (a).
608 Such as biothionol, chlorofluorocarbon and chloroform.
609 Cosmetic liquid oral hygiene products for example mouthwashes and breath fresheners, any kind of vaginal product introduced after 6 Feb 1984 must be packaged if intended to be accessible to the public while held for retail sale. (21 CFR 700.25.) A tamper-resistance package maybe an immediate container and closure system or an outer (secondary) container system which has an indicator or barrier to entry and which provides visible evidence to consumers that tampering has occurred when its indicator or barrier to entry has been breached or is missing. To prevent substitution of the tamper-resistant feature after tampering, the indicator or barrier to entry must be distinctive by design (e.g. an aerosol container or breakable cap) or by use of an identifying characteristic (e.g. name, pattern, logo on cap or cartoon seal).
610 The building must be a suitable size, design, and construction and maintained in a clean and orderly manner—see Guide to Inspection.
611 Equipments and utensil used in processing, holding, transferring and packaging must be of appropriate design, size, material and workmanship to prevent corrosion, accumulation of static material and/or adulteration with lubricants, coolants, dirt, sanitizing agents—refer to the Guide.
612 Raw material must be identified, stored, examined, tested, inventoried, handled, and controlled to assure they conform to appropriate standards—guide inspection.
613 Include sample collection technique, specifications, test methods, laboratory equipment, and technician qualifications.
614 To review record of origin, receipt, examination, testing, disposition and use of raw materials to determine adequacy of raw material control.
correct. A receipt must be given for all of these. The compliance staff at the FDA district office then determines from the information collected, and the results of the analysis of samples gathered whether or not a product is adulterated or misbranded. There is Good Manufacturing Practice Guidelines (GMP) to be observed by cosmetics manufacturer and failure to comply to GMP may result in an adulterated or misbranded product. In terms of procedure the duration of an inspection is dependent on various issues, such as the size of the factory and the specific problems being addressed.

Imported products are also regulated by the FD&C Act and their producers must follow its requirements. They undergo examination and sampling when they arrive at the border from the Customs and Border Protection. Adulterated or misbranded products can be refused entry. If this occurs and if it is not possible to make them compliant then they must be destroyed or returned to their country of origin (re-exported). The details of these inspections have their critics. This will be discussed in the next part.

ii) Warning letters

After an inspection is conducted, if the FDA concludes that a manufacturer has considerably violated FDA regulations, then the manufacturer will be notified. This normally takes the form of a warning letter. This letter identifies the breach, such as substandard manufacturing techniques, untrue claims, errors in the directions of use. The letter will notify the producer that the issue must be rectified and give a time limit for this action. The FDA will then check that the problem has been rectified to its satisfaction.

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615 Investigations Operations Manual, subchapter 4.3
616 FD&C Act, section 704(c).
617 FD&C Act, section 201(b).
618 This involves a controversial issue worthy of a separate discussion on its own. It is noted that there is an ethical demand that dangerous goods are not dumped on other countries, particularly third world countries. Although there are instances where goods banned/restricted in one country can be legitimately exported to their original countries (or even another country), according to Howells, this situation must be controlled and such exports only permitted when the importing country is willing to accept the goods and able to assess any risk posed. See Howells, 1998, supra, p. 370.
619 According to Regulatory Procedures Manual, July 2012 Chapter 4 Advisory Actions Exhibit 4-1, ‘a warning letter is a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a warning letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes.’
If a firm has rectified an issue a close-out letter may be issued.\textsuperscript{620} This will only be issued once the problem has been fixed and not merely on an assurance. The FDA will satisfy itself that the problem has been solved by arranging a follow-up inspection. If the breach was not capable of being corrected, then no close-out letter will be issued. The warning letters sent by the FDA are published through the FDA website. An example of when the FDA issued a warning to a firm involved cosmetics that had been adulterated because of microbial contamination.\textsuperscript{621} The microorganism \textit{Burkholderia cepacia} was discovered in Medline Alcohol-Free Mouthwash.\textsuperscript{622} This product was adulterated as defined by Section 601(a) of the Act\textsuperscript{623} because it would have been harmful to consumers.

Another example where warning letters are issued to cosmetics companies is when cosmetic products are labelled with therapeutic claims. There are many skin care products on the market with exaggerated 'anti-ageing' claims such as claims are that the products "counteract", "retard" or "control" the ageing process. Claims that the product will "rejuvenate", "repair", or "restructure" the skin may also be drug claims. A claim such as "molecules absorb and expand, exerting upward pressure to 'lift' wrinkles upward" is a claim of an inner structural changes that would fall under the drug category. It is noted that warning letters issued by the FDA to the manufacturers/distributors of cosmetics are not as many as to the drug and medical devices manufacturers/distributors. For example in 2010, the number of warning letters issued to cosmetics companies/manufacturers was only 5\textsuperscript{624} as compared to 55 for companies producing drugs and medical devices.

The practise of issuance of warning letter by the FDA can be compared to the practise of issuance of Letter of Advice (LOA) by the CPSC to the responsible firm when the CPSC has determined that a product violates a specific statute or regulation for products under the jurisdiction covered by the CPSA. Similar to the contents of a warning letter issued by the FDA to cosmetic firms, the LOA also informs the firm of the specific product and violation involved, requests the firm to take specific

\footnote{\textsuperscript{620}This procedure applies to warning letters issued on or after September 1, 2009.}
\footnote{\textsuperscript{621}http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/WarningLetters/ucm085147.htm. (7 May 2012)}
\footnote{\textsuperscript{622}In the USA, mouthwash falls under cosmetic category.}
\footnote{\textsuperscript{623}21 U.S.C. § 361(a).}
\footnote{\textsuperscript{624}B. Fernández de Córdova Manent and E.F. González Abellán, ‘Quality Control of Cosmetic Products: Specific Legislation on Ingredients’ in Amparo (ed), \textit{supra.}, p. 65.}
corrective actions, and informs the firm of the legal actions available to the Commission in the event the firm does not agree to correct the violations voluntarily.

iii) Recall of Cosmetics

In the USA, cosmetic recalls are part of post marketing activities. A recall is ‘[a] firm’s removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, such as seizure.’ The most significant point with regards to recalls of cosmetics in the USA is that they are voluntary actions taken by manufacturers or distributors to eliminate products that pose a danger or gross deception from the marketplace. This is different to the recall practises conducted by the CPSC for the consumer products it has covered where the Commission has the authority to recall the product if it decides that the firms has failed to take corrective actions mentioned in the LOA, as explained earlier. Here, the FDA as the agency responsible for cosmetics, categorises a firm’s action as a recall (as opposed to a withdrawal) when it determines that the product’s hazard poses a violation of the FD&C Act.

The FDA is not authorised to require recalls of cosmetics, it does however monitor companies that conduct a product recall and may request a product recall if the firm is not prepared to remove hazardous products from the market without the FDA’s request. In the case of where there is a recall on cosmetics, recalling firms are advised to inform the local FDA District Recall Coordinator as soon as a decision is made that a recall is appropriate and prior to the issuance of press or written notifications to customers. As previously mentioned, the FDA has no authority under the FD&C Act to order a recall of a cosmetic; rather, it can only request a firm recall its product. Therefore, compared to the power given to the CPSC who can actually insist on a recall, it seems that the power to recall cosmetics by the FDA is quite weak.

625 Title 21 of the Code of Federal Regulations (CFR), section 7.3(g).
626 Recalls are addressed in Title 21 of the Code of Federal Regulations (CFR), through section 7.40, section 7.59.
628 Available at the FDA website.
629 Ibid.
On the other hand, the FDA still plays an active role in recalls - that is to monitor the progress of a recall. As well as looking over status reports, it can also carry out audit checks of its own to confirm the success of a recall. An assessment will be made of the product’s danger to health and it will ascribe one of three classes to the product in question. Class I indicates that there is a statistically good chance that use of a product will result in serious harm. Class II indicates a situation where the use of a product may cause short-term or treatable health problems and that the probability of serious harm is very low. Class III indicates a situation where the use of a product is unlikely to have any detrimental effects.

If in view of the hazard it is believed that a public notification is necessary, then the FDA will ensure that either the FDA or the firm issues the public notification. If the firm is unwilling to issue a press release, or unduly delays issuing a press release, the FDA will issue one. In addition, when the FDA request a recall, it will develop a recommended strategy for each recall that sets forth how the Agency expects it to be carried out and the necessity for any press release. If the firm itself develops a recall strategy, then the FDA will review and comment on that strategy. Lastly, the FDA ensures that the product is destroyed or suitably reconditioned.

Apart from the role played by the FDA in monitoring recalls of cosmetics, a cosmetics firm’s is responsible to notify their customers. The content, format, and extent of notification should be commensurate with the danger presented by the product and the recall strategy developed for the product. In short, the firm is responsible for carrying out all the steps in order to make the recall process go as smoothly as possible, such as notifying the appropriate FDA district office submitting periodic recall status reports to the appropriate FDA district office so that it may assess the progress of the recall, submitting a statement and plan for public

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630 21 CFR 7.53.
631 21 CFR 7.41.
632 21 CFR 7.3 (m).
633 21 CFR 7.42(b)(2).
634 FDA also issues general information about recalls through a weekly publication, the FDA Enforcement Report [21 CFR 7.50], which provides information on all recalls that have been assigned a classification.
635 21 CFR 7.42(a)(2).
636 21 CFR 7.55.
637 21 CFR 7.49.
638 21 CFR 7.46(d).
639 21 CFR 7.53.
warning (if necessary), conducting effectiveness checks, and being responsible for the disposal of the recalled product. These procedures however are similar to the procedure provided under the CPSC for the consumer products under it.

iv) Regulatory actions

The aim of the FDA regulatory programmes is to ensure conformity with the FD&C Act. There are enforcement actions to correct and prevent violations, remove violative goods from the market, as well as to punish offenders. The type of enforcement activity the FDA uses will depend on the nature of the violation. One of the actions that can be taken by the FDA is the seizure of dangerous cosmetics. Seizure is an action ‘brought against an FDA-regulated product including adulterated and/or misbranded cosmetics within the meaning of the Act.’ The rationale of such an action is to remove specific violative goods from commerce. There are also injunction orders; a court order that requires an individual or cosmetics company to stop selling the adulterated and/or misbranded cosmetics. The FDA can also use criminal prosecution, an appropriate action if there is a serious violation. This kind of violation does not need to show proof of intent and carries a fine and/or up to one year’s imprisonment. Felony convictions which include repeat offenders or fraudulent behaviour; carry a fine and/or up to three year’s imprisonment.

Criminal Fines for FD&C Act Violations

Misdemeanour fines under the Act may reach $500,000 under some circumstances. The Criminal Fine Enforcement Act of 1994 (Public Law 98-596) provides for fines for violations of Federal law. Although it is not part of the Act, the Criminal Fine Enforcement Act of 1994 applies to all fines levied under the Act, as well as other statutes that contain provisions enforced by the FDA.

The following fines are applicable for each offence:

- Up to $100,000 for a misdemeanour by an individual that does not result in death.
- Up to $200,000 for a misdemeanour by a corporation that does not result in death.
- Up to $250,000 for a misdemeanour by an individual that results in death, or a felony.

640 21 CFR 7.42(b)(2).
641 21 CFR 7.42(b).
642 See http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm268127.htm, (last visited 20 June 2012).
Up to $500,000 for a misdemeanour by a corporation that results in death, or a felony.

The maximum imprisonment for a misdemeanour under the Act remains a year for each offense.

In contrast to the sanctions under the CPSC statutes, in enacting the various statutes administered by CPSC, Congress provided specific sanctions which may be imposed against firms that violate any provision of the statutes. What is different compared to the FD&C Act is that the sanctions under CPSA include both civil fines against the responsible firm and individual, which can go up to a maximum of $1.825 million.\textsuperscript{643} There are also criminal fines and imprisonment of the responsible individual(s) for not more than one year. In addition, firms and individuals may be enjoined to stop violating CPSC statutes and regulations, and pursuant to a court order, violative products may be seized to prevent distribution in commerce. It must be remembered, however, that it is very rare that any violation of cosmetics has ended up with criminal fines as mentioned above. In most cases, many are closed after the warning letters have been issued. Similarly, most recalls of cosmetics, although voluntarily done by the cosmetic firms, rarely give rises to further regulatory actions.

v) Voluntary Cosmetic Registration Program (VCRP)
Due to the lack of pre-market approval processes for cosmetics, the FDA developed the Voluntary Cosmetic Registration Program (VCRP).\textsuperscript{644} This system functions as a post-marketing reporting system available to cosmetics manufacturers, packagers and distributors.\textsuperscript{645} It is designed to support the enforcement of the FD&C Act by making available information pertaining to the manufacture and composition of cosmetic products, as well as data regarding consumer adverse reactions. The information will permit the FDA to correlate in a meaningful way the products and

\textsuperscript{643} The maximum penalty amounts are adjusted for inflation every five years. (69 Fed. Reg. 68884, November 26, 2004). Under Section 20 of the CPSA, any person who knowingly violate S. 19 of the Act shall be subject to civil penalties not to exceed $8,000 for each violation except the maximum civil penalty shall not exceed $1.825 million for any related series of violations.

\textsuperscript{644} The program was divided into three parts i) Voluntary Registration of Cosmetic Product Establishments, ii) Voluntary Filing of Cosmetic Product Ingredient and Raw Material Composition Statement iii) Voluntary Filing of Cosmetic Product Experiences. The first and second program became effective in 1972 while the third program became effective in 1974.

\textsuperscript{645} 21 CFR 701.1.
ingredients which are associated with allergic reactions or other injury reports that are alleged to be the result of the use of cosmetic products.646

Cosmetics manufacturers who participate in this programme have the option of choosing to register their establishment on the system or to file a cosmetic product ingredient statement for each product in commercial distributions. By gaining information about commonly used cosmetic ingredients, the FDA's Center for Food Safety and Nutrition (FDA-CFSAN), which oversees the VCRP database, is able to work with the Cosmetic Ingredient Review (CIR)647 in determining which ingredients should receive testing priorities.648

An additional benefit of widespread participation in VCRP is an increased likelihood of consumer protection because the programme provides notification to all programme participants of ingredients that are determined to be harmful.649 These warnings are then taken into consideration by manufacturers, who will often reformulate products so that the potential hazardous ingredients are not included. Although manufacturers, distributors and packagers who do not volunteer and participate gain notice of potentially harmful ingredients through guidance documents and public release statements, the VCRP offers direct communication and ensures that notice is timely.650 It should be reiterated that the VCRP is not a cosmetic approval programme.651 This voluntary programme only applies to sales of cosmetics in the USA with the exception of professional use cosmetics, for example, those used in beauty salons, and clinics; as well as hotel samples, free gifts or homemade products.652 The next part will discuss thoroughly the critics of this voluntary system.

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647CIR is an independent, industry-funded panel of scientific experts that regularly assesses the safety of numerous cosmetic ingredients and publishes its findings. FDA attends CIR meeting in a non-voting capacity. See Part I of this chapter.
649Ibid.
650Ibid.
652Ibid.
4.4 Part III: Analysis of the Self-Regulatory Scheme for Cosmetic Safety in the USA

Introduction

The previous part discussed the legal mechanisms and the activities conducted by the agency in order to ensure that safe cosmetics reach consumers. Having a self-regulatory scheme for cosmetic, this voluntary system is regarded to be a regulatory anomaly by some and as an exemplary success by others - which has been developed from years of collaboration and experience between the FDA and the cosmetics industry. For the proponents of industry self-regulation, they have argued that no industry in the USA has ever been more dedicated to self-regulation or has been more successful than the USA cosmetics industry scheme. Going beyond the voluntary CFTA programme, the industry also showed their commitment to consumer safety, for example, the CFTA noted that ‘[o]ur industry work every day with leading medical and scientific experts to ensure the safety of our products … we start with ingredients that are thoroughly tested and shown to be safe, and then we further test the finished products to make certain they are safe.’\textsuperscript{653} However, the self-regulatory scheme in the USA has also created many debates and issues which might suggest the existence of loopholes in the system. There is a great deal of literature\textsuperscript{654} which claims that such a system is too lenient or not stringent enough, and that within this regulatory vacuum the law has allowed manufacturers to add unlimited amounts of chemicals into cosmetic products without having mandatory testing requirements. Hence in the USA, cosmetics appear to be the least-regulated products on the market.\textsuperscript{655}

4.4.1 The Main Criticisms of the USA Cosmetics Industry Self-Regulation

Drugs and foods are the other FDA-regulated products that are regularly compared with cosmetics. Drugs are regulated differently as they are subject to pre-market approval while cosmetics are only regulated when they are released on the market. Where drug companies are required to register with the FDA, registration for cosmetics companies only operates on a voluntary basis. There is also a mandatory adverse effects reporting by the drug manufacturer to the FDA, while such reporting

\textsuperscript{653}CFTA President’s Message, CFTA, Annual Report of 2005.
\textsuperscript{654}Among them is A. Greff, Jacqueline, ‘Regulation of Cosmetic that are also Drugs,’ \textit{Food & Drug Law Journal}, Volume 51, 1996, pp. 243-271.
\textsuperscript{655}Compared to drug, food etc.
is only voluntary for cosmetic companies. Lastly, it is compulsory for drug companies to follow the good manufacturing practices (GMP) yet for cosmetics, although guidelines for GMP have been prepared by the FDA, the industry is only encouraged to follow them to reduce the risk of adulteration or misbranding. It has also been claimed that cosmetics are ‘the only major products that lacks centres’, i.e. centres for research.656

Following many critiques on the inadequacy and inefficiency of the system, the FDA has admitted its weaknesses and the lack of statutory authorities for regulating cosmetic, particularly its safety. This was acknowledged by the FDA Chief Counsel for Food and Cosmetic at the time; ‘[t]he existing law has some weaknesses ... one of them being that the FDA does not have general authority to obtain manufacturers’ record and safety related data.’657 In a more recent statement, this flaw was recognised by the FDA through its official magazine which revealed that ‘the regulatory requirements governing the sale of cosmetics are not as stringent as those apply to other FDA-regulated products ... [m]anufacturers may use any ingredients or raw material, except for color additives and a few prohibited substances, to market a product without a government review or approval.’658

Despite the fact that the FDA recognised its weaknesses, the cosmetics industry maintained that cosmetics are safe. The CFTA had launched a website entitled ‘Cosmetics Are Safe’ by stressing that ‘[c]osmetics are among the safest of all consumer products. Their continued safety is ensured by ongoing industry voluntary programme, as well as ample FDA authority to regulate.’659 The voluntary programmes initiated by the industry in collaboration with the FDA are also held up as a symbol of cooperation and it was claimed it is the spirit between the industry and the agency that has permitted voluntary programmes to work so well. 660

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656 Greff, op.cit., 1996, p. 248. There are specific centres for other FDA-regulated products, such as for drugs, the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH) for medical devices, and the Center for Food Safety and Applied Nutrition (CDRH) for foods. However, cosmetics are governed under the centre for food.
659 At http://www.cosmeticsaresafe.org/, (last visited 7 February 2012).
contention has, however, been rejected by Newman – ‘[a] voluntary program is just that and no member of industry has to cooperate.’

In 1978, the Government Accountability Office (GAO), a watchdog agency, issued a report contending that regardless of growing evidence some cosmetics may carry a considerable risk of injury to consumers; and that the FDA did not have an efficient programme for regulating cosmetics. The report revealed that the FD&C Act does not authorise the FDA to oblige cosmetics manufacturers to register their establishment or provide data on their cosmetic substances and formulations, file reports of cosmetic adverse effects, nor conduct safety assessment. It further disclosed that the FDA has not been able to assert its authority, largely because it does not inspect the majority of facilities or take product samples. The recommendations given by the GAO; amongst others, was that the FD&C Act should be amended to give the FDA the power to obtain records of testing done by the manufacturers. They also gave recommendation that the FDA should define the term ‘adequately substantiated for safety’ in order to guide the manufacturers on how to conduct proper testing for their products. In 1990, the GAO did a follow-up report disclosing more of the drawbacks of the voluntary compliance scheme.

Among the findings this time was the low percentage of the voluntary registered cosmetics manufacturers with the FDA and a much lower percentage of the filing of the adverse reactions reports. Also, the report exposed the lack of safety assessment data by manufacturers with some manufacturers even refusing to reveal the results of the tests. The report has been seen as further evidence by the Committee of Small Business for the need to strengthen the cosmetics scheme. Through its representative, the Committee criticised the wait-and-watch approach in the regulation and held that, ‘[i]t is quite clear that there are major gaps in the cosmetic safety system ... public health policy should have us get out in front of these

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663Ibid., pp. 26, 49 and 52.
664Ibid., pp. 92-93.
665Ibid., p. 31.
667It was less than 40% of the 2000-2500 cosmetic manufacturers voluntarily registered with the FDA.
668That was only 3% out of the 4000-5000 cosmetic distributors.
669Ibid., p. 4.
670This Committee is directed under the US Senate to be referred all proposed legislation and petitions and other matters relating to small business administration.
problems, rather than waiting until someone is injured and then going in after that.\textsuperscript{671} A response from the CFTA was rather interesting, in that the association dismissed the findings by the 1990 GAO report by countering that no substantial questions were raised relating to cosmetics safety, ‘[w]e don’t think it’s in the public interest to slap more regulatory burdens on the FDA, which has really been stretched to limits.’\textsuperscript{672} They further argued that the GAO reports were misleading, and in particular questioned whether greater participation in voluntary reporting would really be beneficial. It also stated that given that the injury reports included sixty percent of cosmetics marketed, ‘the companies that are filing reports are representative of the industry.’\textsuperscript{673}

Apart from the GAO report, another non-profit, environmental advocacy group, the Environmental Working Group (EWG), stressed their apprehension that the self-regulatory scheme regulating cosmetics offered little protection to consumers. EWG has done a lot of research and has been extensively involved in lobbying for product safety of personal care products. One of their extensive surveys and programmes called ‘Skin Deep’ exposed several major concerns in the current system. It found that cosmetic products contained industrial chemical as their formulations, and that cosmetics and many other personal care products were used by most people everyday.\textsuperscript{674} EWG further highlighted that the FDA did not have the authority to require the safety studies for cosmetics and contended that there was an inadequacy in the self regulatory system citing that the cosmetics industry panel review (CIR)\textsuperscript{675} had only evaluated approximately eleven percent of the 10,500 of cosmetic ingredients.

The EWG then launched an online survey entitled Skin Deep in which the survey found a very shocking result. It contended that under one percent of the 14,000 products reviewed had actually been safety-tested.\textsuperscript{676} The EWG later made a petition to the FDA in July 2004 exposing the findings and requesting enforcement action from the FDA such as recalls or injunctions and seizure, requiring the removal

\textsuperscript{672} Ibid.
\textsuperscript{673} Ibid.
\textsuperscript{675} As explained in Part I of this chapter.
\textsuperscript{676} About Skin Deep, at http://www.ewg.org.reports/skindeep2/info_about.php, (last visited 12 January 2012)
of any toxic impurities, clarification on their safety and investigations into certain ingredients. For the petition and report, the CFTA issued a statement maintaining that cosmetics were safe and pointed out that the EWG findings were ‘in error’ and made several unfounded allegations in the petition.\textsuperscript{677} In an attempt to restore confidence the consumers on the safety of cosmetics and the efficacy of the system of regulating cosmetic, the CFTA later launched a website; www.cosmeticsaresafe.org. They concluded that:

‘[t]he cosmetic industry is committed to providing the highest quality, safest personal care products possible. Constant research into new ingredients and new formulations ensures that the industry provides such products. Cost is never a consideration for safety ... [t]he bottom line for American consumers is that they can have complete confidence that the products they use are safe.’\textsuperscript{678}

Denying the contention made in the ‘Skin Deep’ survey, the website held that the Skin Deep Report was filled with mistakes and unfounded conclusions. They went further by claiming that the Report indicated that many of the listed ingredients were in fact actually ‘named fragments’, and that EWG had inexplicably missed these errors. In their view the Report was worthless and should not be relied upon.\textsuperscript{679} The FDA was also not silent about this. In September 2005, in the final written response to the critics and the petition by the EWG, it argued that the EWG request for enforcement actions was not appropriate. They also contended that the information provided were inadequate and claimed that the fulfilment of the EWG’s other request was not possible at that time due to FDA limitations and other main concerns and thus the petition was rejected.

With regards to the USA scheme for cosmetics, the self-regulatory system has been cited as the greatest concern in the debates mentioned above. In fact, the weaknesses/loopholes or critics over cosmetics have been attributed to the fact that it is self regulated. It can be argued that if cosmetics are under public regulation, most of the claimed problems would not occur. However, as formally demonstrated

\textsuperscript{678}CFTA Response Statement: Cosmetic Are Safe, at http://www.cfta.org.
in the theoretical chapter, self regulation is useful to save costs.\textsuperscript{680} This is particularly true as it is also the case in the USA, as explained in Part I, that the USA decided to put cosmetics under this kind of regime due to budgetary constraints at the time.

Giving the cosmetics industry the power to self regulate also makes sense as the industry has a greater degree of expertise and superior knowledge\textsuperscript{681} in technical practices as well as in innovation. Also, giving the power to the cosmetics industry to self regulate itself means less formalities\textsuperscript{682} are involved compared to those in public regulation.

As was also explained in the theoretical chapter,\textsuperscript{683} the safety assessment of cosmetics is one of the most important elements that should be made obligatory for cosmetics manufacturers, however this is not the case in the USA, where cosmetics manufacturers may use almost any raw material as a substance in cosmetic formulations and market the product without an approval from the FDA with the exception of colour additives and a few prohibited ingredients.\textsuperscript{684} Placing that under public regulation commonly gives the mandatory authority to approve the substances, the CIR however has no such authority. Also, another main criticism of the cosmetics scheme is that the FDA has relied too heavily on CIR for assessments of the safety of cosmetics. This is problematic as there is no definition of what constitutes substantiated safety. It was argued that, `what is acceptable as safe is up to each manufacturer conducting safety testing’.\textsuperscript{685} As an industry funded panel, the EWG claimed that this structure offered little protection for consumers, as they put it, `[i]t is not just the fox guarding the henhouse, it’s the fox designing and building the henhouse.’\textsuperscript{686} The CIR was also attacked as inadequately safeguarding the safety because it safeguarded the industry’s own interest to avoid being thorough in its review. To support this contention, the EWG provided data stating that eighty nine percent of the 10,500 personal care products ingredients remained untested by CIR.

\textsuperscript{680}See Ogus, \textit{op.cit.}, 1999, p. 591 that states ‘delegation to self regulatory agency should reduce the principal’s cost of regulation.’

\textsuperscript{681}See Grajzl and Murrel, \textit{op.cit.}, 2007, p. 521. As explained in Part III, the theoretical chapter.

\textsuperscript{682}Ogus, \textit{op.cit.}, 1999, p. 591. Also see Heeks and Duncombe, \textit{supra}, 2001, p. 2.

\textsuperscript{683}Part III of the theoretical chapter.

\textsuperscript{684}Mentioned in Part I of this chapter.


Again, this was defended by the CFTA claiming that CIR was an independent body of experts who published their findings in peer-reviewed journals, and held that they believed such an open and public process included not only representation from the government but also consumers; that they also considered all available data in the appropriate manner to substantiate the safety of cosmetics before they were released on consumers.687

Other Criticisms of the Cosmetics safety Regulation in the USA

The USA's cosmetic labelling is also subject to criticism. It has been argued that, although the current system of cosmetics requires certain labelling information, and duty to warn by the cosmetics firms in the event that they do not test the safety of their products, this is still regarded as insufficient. According to Page and Blackburn,688 they held that the flaw of the warning lies in the language used. Instead of warning about the potential harm the products can bring without any testing assessment, the warning merely advises consumers that ‘products have not been safety tested.’ As many consumers in the USA mistakenly presume that the FDA test the safety of cosmetics, Page and Blackburn have concluded that consumers would be better protected if they were simply made aware that most cosmetic are not tested for safety. Also, they added that based on the FDA's prior enforcement record, the cosmetics industry will probably not adhere to the warning requirement and the FDA ‘will not enforce it.’689

As demonstrated in Part I, with regards to provisions of ‘misbranded’ cosmetics in the FD&C Act, it has been claimed that the provisions have generally produced little litigation.690 The misbranding cases that have arisen have primarily addressed the issue of cosmetic/drug distinctions. The reason given for the relatively low number of cosmetics misbranding cases is that the burden of proof lies on the FDA to show the misleading nature of the claims, while for the drug, the FDA can shift the burden of proof to drug companies by rejecting the pre-market applications.691

688 Joseph Page and Kathleen Blackburn, supra, p. 808.
689 Ibid.
Further, it has also been argued that ‘the FDA's response to the difficult policing task of cosmetics claims has been to give the category a relatively low priority.’\textsuperscript{692} Not only that, it should also be noted that the Federal Trade Commission, a body that is responsible for regulating cosmetics advertising rarely pursues legal challenges to cosmetics claims.\textsuperscript{693}

As well as criticisms over CIR and labelling/duty to warn requirements, there has also been criticism over the monitoring exercise conducted by the FDA. The FDA has the authority to conduct inspections of cosmetics firms at reasonable times, in a reasonable manner, and without prior notice in order to ensure compliance with the applicable laws and regulations, to determine whether cosmetics are safe and properly labelled, and to identify possible health risks and other violations of the law. However, it has been argued by O'Reilly that, notwithstanding the fact that the FDA has such authority, cosmetics facilities are not frequently inspected due to limited resources.\textsuperscript{694}

The system of self-regulation inevitably places some responsibility on consumers in that they are responsible for remaining informed, and being discerning and vigilant in order to safeguard their own health and safety. Due to this the FDA has been criticised and accused of abandoning consumers – ‘[p]ublic health is in the hands of the impotent agency, safety testing is voluntary, safety decisions are at the discretion of the individual companies and the burden of choosing safe cosmetics falls squarely on the shoulders of each consumer.’\textsuperscript{695} However, in discussing consumers in the USA, it is imperative to mention that they enjoy more autonomy compared to consumers in many other jurisdictions. For example, it has been suggested that Americans are more litigious than the Europeans.\textsuperscript{696} They have been known for the large number of cases in product liability claims. Product liability in the USA has its own course in the law curriculum, and the fact case numbers are so big means many American lawyers earn their living from litigating product liability. As Howells states that this is because the American legal environment is more

\textsuperscript{692}James T. O’Reilly, \textit{Food and Drug Administration 17-14}, 2\textsuperscript{nd} Edition, 2005.
\textsuperscript{693}\textit{Ibid.}, pp. 17-32.
\textsuperscript{694} \textit{Ibid.}
\textsuperscript{695}Consumer Update, ‘FDA admits inability to ensure the safety of personal care products,’ at http://www.ewg.org/reports/skindeep2/findings/index.php?content=FDAfails to protect (accessed 12 May 2012)
conducive to litigation. Also, since there is no liability for the other party’s costs in an unsuccessful claim it means there is no restriction on ‘trying one’s luck’ in the claim. The other important reason for the big numbers of product liability litigation in the USA is the level of damages which are considerably higher than elsewhere, such as the award of punitive damages as well as class action. This in itself acts as a magnet for litigants - because of this, the risks of producing dangerous products are sometimes mitigated by adverse publicity. For example, it was reported that in 2008 lawsuits were filed against several personal care companies in the USA whose products allegedly contained several carcinogenic substances without any reasonable warning. That is presumably the reason why certain cosmetic lawsuits ended up in a settlement which also commonly involved a high amount. For example, a manufacturer of Brazilian Blowout hair treatment products paid $4.5 million for a class action lawsuit settlement following complaints concerning formaldehyde in the product’s formulation.

Despite the facts given above, however, it must be remembered that if a manufacturer or producer of cosmetics produces unsafe cosmetics, they may suffer financially, but it is the injured consumer who suffers the physical harm, which can sometimes be lethal. Prevention is also, always much better than cure.

4.4.2 The California Safe Cosmetic Act of 2005 (CSCA)

In 1997, the FD&C Act’s cosmetics provisions were criticised by Senator Edward Kennedy where he highlighted the importance of state cosmetics regulation, and said that the agency should not interfere with the right of states to act against cosmetics hazards and to protect their citizens independently. One of the states that responded to this call was California. California has been at the forefront of the campaign to ensure cosmetics safety and to increase consumer knowledge of potential cosmetics risks. In February 2005, the State Senator Carole Migden

701 G.Kay, supra, 2005, p. 67
introduced a bill that would require cosmetics companies to report products containing chemicals known to increase the risk of cancer or reproductive toxicity. Despite an extensive lobby by the cosmetics industry to defeat the bill, Governor Schwarzenegger ultimately signed it into law on October 8, 2005. The bill is codified as the California Safe Cosmetic Act of 2005\footnote{2005 Cal SB 484.} which became effective on 1\textsuperscript{st} January 2007. The goal of the Act is to protect consumers and beauty care workers from exposure to the harmful chemical substances in cosmetic products. California’s Department of Health Services (DHS) was mandated by the Act to require cosmetics manufacturers to provide a complete list of any chemical identified by the state as causing cancer or reproductive toxicity. Also, the DHS was authorised to determine whether any cosmetic product has been adequately substantiated for safety in accordance with the federal regulations and to refer those products in violation to California’s Attorney General and the FDA for possible action.

The CSCA is now considered a landmark in the effort to guarantee the safety of cosmetics in the USA. As the first state with such a movement, the CSCA is not without its critics. It has been argued that such a law will lead to over-regulation and be an unnecessary diversion of public health resources, given that, ‘in a state that has real problems with energy prices, unaffordable housing and huge fiscal deficits, why the preoccupation with an issue that poses, at most, the \textit{de minimis} risks to consumers?’\footnote{Henry I. Miller, ‘Hysteria over Cosmetics; Why Would California Lawmakers Yearns For European Style-Over Regulation?’ \textit{The Orange County Register}, April 24, 2005.} The cosmetics industry, in vigorously opposing this law, also expressed its dissatisfaction by stating that the CSCA will overburden the manufacturer and force them to divulge important trade secret formulations.\footnote{Simon Pitman, ‘Battle over California Cosmetics Bill Hots up,’ Cosmeticsdesign.com, 21 June 2005, at http://www.cosmeticsdesign.com/Formulation-Science/Battle-over-California-cosmetics-Bill-hots-up (last visited 6 February 2012). Also, see another article by Pitman on the CSCA, California Cosmetics Bill Becomes Law, Cosmeticsdesign.com, 12 October 2005, at http://www.cosmeticsdesign.com/Market-Trends/California-cosmetics-Bill-becomes-law, (last visited 6 February 2012).}

The proponents of the Act have responded by asserting that the law fills an important regulatory gap and is of national significance, ‘[f]or decades the FDA has allowed the cosmetic industry to police itself. Now, California is stepping into the breach of order to address the latest science on chemicals and human health.’\footnote{Press Release, Campaign for Safe Cosmetics, p. 204.} The EWG has also praised the Act’s emphasis on disclosure, stating that it may be legal for...
companies to use cancer-causing chemicals in their products but now Californian consumers will have the unique right to know about the potential harmful ingredients.706

4.5 Conclusion: Is self regulation adequate in the existing cosmetics safety scheme in the USA?

As demonstrated in this chapter, cosmetics in the USA are subject to a self regulatory voluntary system. This system of regulation has caused much criticism especially from consumer safety advocates, who state that it has created a regulatory vacuum and have urged that it be replaced with tighter regulation. Apart from the intention of Congress to save costs and to limit formalities, another main factor contributing to such a system of regulation is the attitude that cosmetics are generally safer than other products regulated by the FDA, and thus that the FDA should not be burdened given its other high priorities.

Despite many efforts to amend the existing system, Congress has failed to pass legislation granting the FDA greater authority to regulate cosmetics. The CSCA however, was the first movement that changed the course of current cosmetics legislation in the USA by requiring cosmetics firms to publicly disclose potential toxic ingredients contained in their products. The Act also provides new enforcement mechanisms by allowing state agencies to require manufacturers to submit safety data. This effort has been hailed as a positive move towards the tightening of the safety of cosmetics. It has been reported by the Chief California Safe Cosmetic Program707 in 2010 that despite teething problems, such as lack of resources and the legislative language, after several years of implementation, it is now regarded as a success. This is evident from the fact that, up until 31 August 2010 alone, 25,000 compliance submissions have been made.708 Also, in terms enforcement, there were 452 companies reported for non-compliance. There are still ongoing efforts being made, such as the development of cosmetics website and databases called ‘Public Page,’ which is thought to help both producers and consumers especially in identifying chemicals and providing cosmetics information. As for the general regulation of cosmetics in USA, they remain essentially unchanged.

706 Pitman (for the CSCA), California Cosmetics Bill Becomes Law, supra.
707 J. DiBartolomies, Michael, ‘A First Step Towards Healthier Personal Care,’ 2010
708 The report however did not specifically mention if the reported cases are based on non-compliance and what actions have been taken to address the non-compliance.
Discussing cosmetics safety, although it might not be as strict as regulating drug products due to their inherent dangerous nature, the fact that it still represents a risk does not mean it should be underestimated. In the USA, having the current system, despite the fact that product liability claims can be made, it must be remembered that some producers do not feel the full impact of product liability, in which they may provide safety level of cosmetic at a less than optimum level, even if one can accept that product liability rules are capable in theory of producing the desired result; safer cosmetic products.\textsuperscript{709} Also, it is possible that the leniency of the cosmetics safety law in the USA, its self-regulation, might also bring about the possibility of trade barriers - for example the difficulties in entering the stricter markets of other jurisdictions, such as the EU. For cosmetics, because these products have become more and more complex and heterogeneous, stricter rules are needed. Perhaps it is timely for the USA to make a shift away from its current rules for regulating cosmetics towards greater protection for consumers and their health.

\textsuperscript{709} Explained in the theoretical chapter, part II.
Chapter 5: Regulation of Cosmetics in Malaysia

5.1 Introduction
Malaysia is a country situated in Southeast Asia. One of the most significant events in the history of Southeast Asia was the formation of the Association of Southeast Asian Nations (ASEAN) on 8 August 1967. Malaysia was one of the original members of ASEAN together with four other countries namely Indonesia, Thailand, Singapore, and the Philippines.\textsuperscript{710} The objectives of the formation of ASEAN were twofold, first, as a means to promote peace and stability in the region,\textsuperscript{711} and, second, to prevent the spread of communism. Although at that time the main impetus of the formation of ASEAN was political in nature, economic cooperation was also high on the agenda of the organization. The ASEAN Free Trade Area or AFTA, which was embodied earlier in the Singapore Declaration, was signed in 1992 by the ASEAN heads of government at the Fourth ASEAN Summit Meeting held in Bangkok. Its objective was to increase the region’s competitive advantage as a single production unit. The plan of AFTA was to remove all the existing tariffs by means of the Common Effective Preferential Tariff (EPT) scheme by January 2002.

The development of international trade has put the harmonisation of regulations high on the list of priorities in many regions, and in ASEAN the situation is no different. As cosmetic products are among the currently popular products that attract many consumers, massive sales of such products have resulted all over the world. Consequently, many cosmetic producers in ASEAN countries had shown their eagerness to make a profit by producing cosmetics that sometimes lead to the introduction of cosmetic products, the safety of which are uncertain. Following that, there were many reports of cases involving hazardous effect of cosmetic, especially with regards to whitening products.\textsuperscript{712}

As the EU had embraced the globalisation of cosmetics regulation it was high time for ASEAN to harmonise and to eliminate trade barriers between the member

\textsuperscript{710} Later, ASEAN was joined by Brunei on 8 January 1984, Vietnam on 28 July 1995, Laos and Myanmar on 23 July 1997, and Cambodia on 30 April 1999 which makes ASEAN comprised of 10 countries altogether.

\textsuperscript{711} At that time, Southeast Asia was divided by ideological conflict and war. Coupled with territorial disputes and racial tensions between neighbours, there was a possibility that the differences could degenerates into a full-blown armed conflict leading to a prolonged fragmentation.

countries. Ultimately, it encourages the idea of having government and industry joint responsibilities for ensuring products are safe and effective when they reach the consumer. Differences of cosmetic regulations meant there was more than one definition of ‘cosmetic’ and it was used differently from country to country. Similarly, in regard to cosmetic ingredients, there were different restrictions on the ingredients in different countries. These differences were eliminated by the introduction of the ASEAN Cosmetic Directive 2003 which was adapted from the EU Cosmetics Directive. Being a member of ASEAN, Malaysia was obliged to implement the new scheme into its cosmetic safety regulation - which has been transposed into Guidelines for Control of Cosmetic 2009. Although called guidelines, and although they have not yet been transposed into law, these Guidelines are mandatory for industry and they have a binding effect. The most significant difference with the old practice is the introduction of product notification replacing cosmetics registration which needed approval from the cosmetics authority. The new system means such registration is no longer applicable. This chapter analyses the implementation of cosmetics safety regulation in Malaysia through its new system.

This chapter is divided into 3 parts. Part I explains the background of the history of the introduction of the new harmonised system into ASEAN. Here, the nature and guiding principles underpinning cosmetic safety regulations in ASEAN is highlighted in order to provide a clear picture of how the new policy has been introduced. Then the background of Malaysian legislation is identified. In order to achieve an integrated market for the whole ASEAN, harmonisation between the member countries was seen as an impetus to develop the cosmetic industry and at the same time to achieve the similar safety standard for the consumers of the region. Consequently, all the member countries have agreed to sign the agreement to harmonise their cosmetic regulatory scheme. There are some elementary discussions on the ACD being deployed in ASEAN. The effect of the harmonisation also is analysed in this part.

Part II will discuss the pertinent changes of the implementation of the ACD in Malaysia. It seems that the implementation is the most complicated part of harmonisation of safety particularly when it is different between each country. At this juncture, the member countries need to transpose the ACD into their national laws so that they cannot restrict their market access to products that fulfil all requirements. Lastly, as the new policy is being put into practice, it is not exempt
from some issues and challenges especially in implementing such a new system. These are examined in Part III of this chapter. Before going into a deeper discussion on cosmetic safety regulation, it is important to understand the background of product safety regulation in Malaysia first.

5.2 **Part I: Product Safety and Cosmetic Safety in Malaysia**

Introduction

The study of product safety in Malaysia started several decades ago. Product safety came into being due to the alarming and increasing number of preventable home accidents relating to consumer products. With the advances in technology, consumer products on the market increased in complexity and sophistication. The maxim *caveat emptor* is no longer applicable in situations where a reasonable examination of the product will not reveal the inherent defects or hazards. In discussing the safety of products in Malaysia, food safety is given considerable attention. Perhaps this is because the consequent effects of eating unsafe food may result in more spontaneous and dangerous effects such as food poisoning in the short term and present even more serious implications in certain situations. Another product that has recently had safety issues is toys.

5.2.1 **Background of product safety development in Malaysia**

The study of consumer protection safety in Malaysia is rather convoluted as it falls under the remit of various government agencies and is dependent upon the consumer related function performed by the respective Ministry. This indicates that there was no general law on product safety in Malaysia that provides for the general safety of consumer products, in fact the law on product safety in Malaysia is subdivided into several legislative instruments dealing with specific products. For

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714 This maxim comes from Latin words to mean ‘Let the buyer beware.’ The legal principle means that, unless the quality of a product is guaranteed in a warranty, the buyer purchases the product as it is and cannot hold another liable for any defects.

715 Malaysia has several statutes in operation governing food namely Food Act 1983, Food Regulation 1985, and Food Analyst 2011.

716 For the increasing concerns over toy safety in Malaysia, the Malaysian Government has published two consumer protection regulations gazetted on 30 July 2009 and came into effect on 30 January 2010 to mandate the implementation of toy safety standards and conformity mark for sale of toys in Malaysia. The said regulations are the Consumer Protection (Safety Standards for Toys) Regulation 2009 and Consumer Protection (Certification of Approval and Conformity Mark of Safety Standards) Regulation 2009.

717 Sothi Rachagan, *op.cit.*
example, the Electrical Inspectorate Act 1983 and Electrical Inspectorate Regulation 1984 provide measures of protection for consumers of electrical installations and appliances. Other regulations that deal with consumer safety are the Food Acts 1983 and Food Regulations 1985, the Pesticides Act 1974, the Poison Act 1952 and the Radioactive Substances Act 1968.

From the consumer movement in Malaysia, many have urged and suggested bringing together the various measures to address the weaknesses and challenges of the consumer market.\footnote{For example, Malaysia Association of Standard Users is one of the most active consumer associations that urges for a more stringent product safety regulation. See http://www.standardsusers.org/standardsusers/index.php?option=com_content&view=article&id=308:product-safety-concerns&catid=60:opinions-of-the-president&Itemid=86,(last visited 8 February 2012).} In consequence of that, in 1999, the Consumer Protection Act\footnote{Malaysian Act 599.} (CPA) was introduced; the Act serves as the main law and provides remedies and protection to the consumers. For the instruments that have no specific legislation, the proviso in the CPA, specifically in Part III of the Act has become the remedial clause that deals with product safety. This part of the Act draws upon the Trade Practices Act 1974 of Australia, the Fair Trading Act 1986 of New Zealand and the Consumer Protection Act 1987 of the United Kingdom. Therefore, in Malaysia, it is reasonably clear that the safety of products is being protected by the general proviso in the CPA that also includes services. It says:

(1) The Minister may by regulations prescribe the safety standards in respect of—
(a) any goods or class of goods; and
(b) any services or class of services,
and may prescribe different safety standards for different goods or services, or classes of goods or services.

(2) The safety standard in relation to goods may relate to any or all of the following matters:
(a) the performance, composition, contents, manufacture, processing, design, construction, finish or packaging of the goods;
(b) the testing of the goods during or after manufacture or processing;
(c) the form and content of markings, warnings or instructions to accompany the goods.
(3) For the purposes of subsection (1), the Minister may, on the recommendation of the Controller and with consultation with the competent agency -

(a) adopt in whole or in part the safety standard used by the competent agency; or

(b) obtain advice from experts in the relevant field.

(4) Where no safety standard has been prescribed under subsection (1), the person supplying or offering to supply the goods or services shall adopt and observe a reasonable standard of safety to be expected by a reasonable consumer, due regard being had to the nature of the goods or services concerned.

(5) In this section, “competent agency” means any person, body or authority that has determined or has the expertise to determine safety standards for any goods or services.

(6) This Part shall not apply to healthcare goods and food.

(7) For the purpose of this Part, “healthcare goods” means any goods used or intended to be used, provided or intended to be provided or prescribed or intended to be prescribed in the provision of healthcare services.720

In Malaysia, the existing regulations relating to product safety have been analysed by some Malaysian academics such as Sothi721 and Krishnan.722 Their main concern is that the traditional rules on product safety in Malaysia do not give proper protection to the consumer. What Sothi observed in the course of his research is that the development of the product safety regime in Malaysia was quite parsimonious compared to that of the United Kingdom, the United States and Australia. He considered that the alarming and increasing trend of unsafe products could threaten Malaysian consumers and that more stringent regulations were required to change the situation. Therefore, the question arises as to whether the existing law on product safety is adequate and capable of dealing with all the modern safety problems of consumer products. Certainly, nowadays, with the existence of numerous products of greater sophistication and complexity on the market, it is uncertain that everything is fully covered under the law. It is submitted that having an Act in Malaysia specifically for product safety can provide better protection in so far as product safety is concerned. It is thought that the European Community has a

720Section 19 of the Consumer Protection Act 1999 of Malaysia.
well-developed regime of product safety, a Directive on General Product Safety sought to fill any gaps with respect to consumer products by placing a general safety requirement on producers and distributors of all consumer products. In other words, the existence of a specific law on product safety will act as a safety-net for risks not covered in specific regulations or at least to provide obligations such as notification and reporting that are not found in specific regulations.

As far as safety legislation is concerned, there are some assumptions that can be made as to why the regulators in Malaysia do not introduce general safety legislation. It is presumed that as far as the safety of the consumer is concerned, there are as yet no major cases that have affected the country, or even if any case occurs, the sectoral regulation is adequate to govern the situation at hand. In addition, an assumption can also be made that there is a tendency/capability that Malaysian regulators have other priorities than resolving consumer safety since the CPA already acts as a remedy for consumers. Further, another assumption that can be made concerns the perspective of the consumers’ themselves regarding their awareness. Compared to the consumer awareness in developed countries such as the UK and the USA which have a stronger consumer voice, some literatures proved that consumers in Malaysia are a more vulnerable group. In the event of any such incident, they are rarely reported to the authoritative bodies. Some of them perhaps have encountered the problem concerning safety of product but rather chose to just ignore or being silent thinking taking action was a waste of their time and resources. It has been stated by the Dispute Resolution and Policy Manager of the National Consumer Complaints Centre of Malaysia (NCCC) that ‘some called seeking advice but they don’t take the next step as they feel their complaints are unimportant or they aren’t aware of their rights’. She further said that from approximately 50 calls daily that the Centre received, not even half are followed through by consumer themselves.

723 See the discussions in the theoretical and the EU chapters.
725 The NCCC Bulletin, the 5th Complaintfest, 2011.
726 Ibid.
5.2.2 Cosmetic Products in Malaysia

Among consumer products that have increased their sales tremendously in ASEAN are cosmetics. As taking care of physical appearance is the global trend, in Malaysia similarly, people have started to become more conscious about beauty. The Cosmetic, Toiletries and Fragrance Association of Malaysia (CTFA) reported in 2004 that twenty three percent of the sales of cosmetics in Malaysia are made up by the skin care segment.\textsuperscript{727} Among the skin care segment, whitening products are the products that have most increased in use especially among Malaysian women. A New York Times report in 2006, which quoted a survey done by Synovate,\textsuperscript{728} a market research company, stated that four out every ten women in Malaysia use whitening products. Another study claimed\textsuperscript{729} that some Asians tended to overdo the usage of these, and that they randomly picked products to be used without thoroughly investigating their usefulness and the possible negative outcomes of their usage.\textsuperscript{730} This situation is not alien to other ASEAN countries such as the Philippines and Thailand. Another concern is the issues pertaining to whitening products. Many cosmetics producers especially local manufacturers, produced a wide range of whitening products, in which many put illegal substances.\textsuperscript{731} A study\textsuperscript{732} held that there are four groups of cosmetics brands in Malaysia: local brands that are owned by local companies; local brands owned by local manufacturers but manufactured abroad; foreign brands owned by international firms but that manufacture their products locally; and lastly, foreign brands owned by international firms and manufactured abroad. The study highlighted that most non-compliant cosmetics were produced by the first two groups.

Presently, in Malaysia, the relevant legislation concerning cosmetics is the Control of Drugs and Cosmetics Regulations 1984, which was promulgated under the Sale of Drugs Act 1952\textsuperscript{733} (revised 2006). Under Part II of the regulation, the Drug Control Authority is established for the purpose of carrying out the responsibilities as the relevant authority. There is also the National Pharmaceutical Control Bureau.

\textsuperscript{727}CTFA Annual Report Year End 2004.
\textsuperscript{728}It can be accessed at http://www.docstoc.com/docs/34037996/MALAYSIA (5 April 2011)
\textsuperscript{729}Nordin Mansor, Desnika Efni Mat Ali and Mohd Rafi Yaacob, \textit{ibid.}, p. 273.
\textsuperscript{730}\textit{Ibid.}
\textsuperscript{731}For example see article of New Straits Times, Tuesday, March 25, 2008 entitled ‘Face Scarred by Beauty Product.’
\textsuperscript{732}Raihani Md Kasim, \textit{The Influence of Ingredients towards Malaysian Consumers’ Preference on Facial Care Moisturiser: Case Study on Malacca Consumer},’ a master thesis.
\textsuperscript{733}Act 368 of Malaysia.
or known as the NPCB, which acts as its secretariat. This bureau is responsible for the registration of drugs and cosmetics and the licensing of manufactures, importers and wholesalers.

5.2.3 ASEAN Cosmetic Harmonisation

Following the demands of the cosmetics industry, ASEAN gathered to hear the cosmetics issues that have affected the ASEAN countries. One of their main apprehensions was the use of illegal substances in cosmetic products by certain companies. This has raised several concerns as it involves the question of safety to consumers in ASEAN. Another issue concerns the fake and counterfeit cosmetics that are sold everywhere and that are easily available to consumers. In addition, the industry complained about the difficulties in selling their cosmetic products to other countries in the region due to the differing requirements and safety standards. They claimed that cosmetics that have been tested in ASEAN for ASEAN people are better for them as they have a similar type of skin, and the weather is also relatively similar, therefore it is good if they can market their products across other ASEAN countries. However, they could not do that since trading between ASEAN countries was difficult due to many barriers. Overall it was felt that these issues were present due to the differing legislation in each ASEAN country. This ultimately resulted in barriers to trade.

To rectify this, ASEAN brought in the ASEAN Free Trade Area (AFTA), which was created in recognition of how important regional trade and competitiveness is and could become. The ASEAN Consultative Committee on Standard and Quality (ACCSQ) was then established to create a uniform product standard and technical requirement to facilitate trade, and cosmetics regulation was central to this move.

The Committee set down that before creating a uniform product there must be some guiding principles in cosmetic legislation in ASEAN.\textsuperscript{734} In the Cosmetic Congress which was held in Florence in 1998,\textsuperscript{735} a representative from each region was called. The ASEAN representative highlighted the three guiding principles of


\textsuperscript{735} Florence Cosmetic Congress organised by COLIPA, held in Florence, Italy, June 1998. The Congress was on the global harmonization for cosmetic regulation attended by more than 250 delegates from 35 countries in the world.
cosmetics regulation in the region. The needs of the consumer was the first consideration, in terms of safety and quality. This was the primary priority for the cosmetics industry in which consumers must be provided with choice and freedom in their ability to choose the cosmetic product that best suits them. They must have adequate information to help them determine the safety, efficacy, and basis of the claimed benefits of the products. Second, there must be government regulatory agencies that have responsibility for cosmetic products to ensure the safety, efficacy and quality of these on the market. This mandate can be efficiently served by actively monitoring the products at the time of manufacture and when placed in the market. They should also have the authority and the resources to aggressively enforce cosmetics laws. Lastly, in ASEAN, the objectives of free trade and the needs of ASEAN consumers guide the harmonised regulatory system. A common definition of what constitutes cosmetic products and perhaps common lists of ingredients are the basic enabling elements for a harmonised working regulatory system in ASEAN.736

As previously mentioned the ASEAN cosmetic industry continues to address the market demands in ASEAN, ASEAN has welcomed their interest and support to complete its vision of AFTA. In fact, the ASEAN Cosmetics Association (ACA) has been instrumental in bringing to ASEAN’s attention the need to harmonize the ASEAN regulatory systems for cosmetic products so that they do not pose technical barriers to trade. An ad hoc Working group on the harmonization of the technical regulations for cosmetic products in ASEAN was created by the ASEAN Consultative Committee on Standard and Quality (ACCSQ) to study the harmonization of cosmetic regulation in the region. This group is composed of the representatives from ACCSQ, the Board of Health in ASEAN countries as well as the representatives from the regional cosmetics association and industry, for which the Philippines acted as the country chair at that time. This group aimed to study the existing cosmetic regulation in ASEAN countries and eventually formulate a plan for harmonization one year after its meeting, which was in July 1999.

By July 1999, the ad hoc working group had submitted a report to the ACCSQ on the results of its study of the cosmetic regulation and systems. The report concluded that a system of harmonization of standards combined with mutual recognition is the appropriate answer. The thrust of harmonization principles is that

the governments and industry moves towards a more efficient industry that takes full responsibility for the safety of its products. More importantly, both governments and industry have a joint responsibility for ensuring that products are safe and effective when they reach the consumer.

In relation to the safety of cosmetics, the problem of unsafe cosmetics is a global one and ASEAN is not exempt. Specifically the problem lies in the sale of unsafe cosmetics or those whose safety is uncertain. It is noted that ASEAN people are more interested in having whiter/fairer skin. Many producers use potentially harmful substances in the cosmetic formulations because it saves money and gives quicker effects. In addition, there are also problems concerning counterfeit cosmetic products being sold in many countries. As a result, ASEAN decided that in order to provide a better standard of safety of cosmetic products to consumers, product standards would eventually need to be harmonised.

5.2.4 ASEAN’s Mutual Recognition Arrangements and ASEAN’s Harmonised Cosmetic Regulatory Scheme (AHCRS)

In order to resolve the above problems, ASEAN realised the importance of finalising Mutual Recognition Arrangements and took the decision to standardise procedures and technical regulations to increase consumer safety and promote trade. Subsequently, collaboration was agreed, namely, the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS), which was signed on 2 September 2003. The Agreement provided two objectives for this harmonisation. First, to improve cooperation amongst Member States in ensuring the safety, quality and claimed benefits of all cosmetic products marketed in ASEAN, and second; to remove barriers to trade in cosmetic products amongst Member States through harmonisation of technical requirements, Mutual Recognition of Product Registration Approvals and adoption of the ASEAN Cosmetic Directive.

The Scheme seeks to eliminate barriers to trade by standardising regulatory and technical requirements across ASEAN without compromising consumer safety

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737 As mentioned in chapter 1.
738 The potentially harmful substances used including hydroquinone acid, retinoic, and ammoniated mercury.
739 See the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme, signed on 2 September 2003. Objective 1, p. 10. It can be assessed via http://www.aseansec.org/20707.pdf, (last accessed 12 June 2012).
740 Ibid.
and quality. This would allow the free flow of products across the region and promote ASEAN’s competitiveness. The significant core point of the AHCRS of the harmonized scheme is the adoption of the ASEAN Cosmetic Directive (ACD) to the member states, which lays down the requirements for cosmetic products to comply with in all signatory countries. The objective of the ACD is to explicitly safeguard the safety of cosmetic products for consumers. This has been spelt out in the article 3 of the ACD which says:

'A 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.'

5.2.5 The Adoption of the EU Cosmetics Directive to Strengthen Cosmetic Safety

The most significant aspect of the harmonisation of cosmetic regulations is that the ASEAN Cosmetic Directive (ACD) is based on the EU Cosmetics Directive (EU CD). In fact, all of the amendments and the technical adaptations to the EU CD are adapted by the ACD. In the wording of Article 4(1) of the ACD it is stated;

'Member States shall adopt the Cosmetic Ingredient Listings of the EU Cosmetic Directive 76/768/EEC including the latest amendments.'

From the provision, it seems that any amendment that affects the ingredient listing in the EU Cosmetics Directive is automatically applicable to ASEAN (and that also means Malaysia). In addition, there has been significant cooperation between the two regions and EU has assisted ASEAN in its collaboration effort in the recent years. The implementation of the ASEAN Cosmetics Directive was supported by the

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741 Ibid.
742 EU Cosmetic Directive(76/798)
743 The adoption includes all of the annexes. see Article 4 (2), 4(3) and 4 (4)
EU through the APRIS\textsuperscript{744} programme. Undoubtedly the ASEAN Cosmetics Directive is one of the first concrete examples of an attempt at economic integration among ASEAN countries. Receiving assistance from the EU, ASEAN has created the Cosmetic Directive. This is currently being transposed across the ASEAN countries. Under the Cosmetics Directive, the ASEAN regulators as well as the cosmetic industry have decided to common standards for cosmetic products, and common rules for compliance safety assessment and marketing.

The ACD limits restrictions on the trade of cosmetic products by streamlining technical controls, promoting mutual recognition in terms of product registration, and establishing coordinated market surveillance systems particularly to ensure that the safety, quality and claimed benefits of cosmetic products sold to the consumers are of the same standard between the countries. Considering the cosmetics ingredients themselves, one finds different restrictions on ingredients in different countries around the world. For example, a preservative may be used at one level in one country and at another in a different country. Similarly, concerning labelling, one finds different warning requirements, and the ingredients listing requirements differ. It must be noted that although the framework and all substantial safety elements have been borrowed, the procedure of implementation are quite different.

Now, it is understood that ASEAN has adopted the EUCD in order to upgrade safety standards in cosmetics as well as to solve problems in trade barriers, there is however one crucial question that needs to be addressed, that is, how far the harmonization of cosmetic regulation introduces the safety standard into ASEAN countries. Although cosmetic safety regulation first gained the acceptance in the Federal Food, Drug, and Cosmetic Act of the USA, it is now an accepted part of the legal regime for consumer protection in most countries. Their regulatory frameworks are obviously different, albeit the aim is fairly similar, i.e. to provide safer cosmetic products to the consumers.

\textsuperscript{744}APRIS or the ASEAN-EU Programme for Regional Integration Support aims at assisting the ASEAN Member States in strengthening Post Market Surveillance (PMS) including an assessment of the legal, institutional and human resources required to establish and operate PMS systems in each member states, by including technical assistance and training, with specific emphasis on compliance issues in respect of product safety and efficacy, the drafting of Product Information Files and product liability for national regulatory authorities and the Cosmetics industry,
5.2.6 Model for ASEAN Cosmetic Directive

Having examined the factors leading towards harmonisation of cosmetics regulation in ASEAN, one more essential question needs to be answered - why has the EU Directive been chosen as a model and not some other regulation, such as from the USA?\(^\text{745}\)

First it can be submitted that the EU is considered to be a leader in the cosmetics industry and in initiating new cosmetics policies.\(^\text{746}\) For example, Bach and Newman\(^\text{747}\) suggest that the EU that has tenaciously ‘shaped’ global rules for cosmetics,\(^\text{748}\) compared to other large market, such as the USA. Also, the development of cosmetics regulation in the EU provides a reference to many countries. For example, a study\(^\text{749}\) on the comparative cosmetics legislation found that around 30 countries have adopted the EU lists\(^\text{750}\) which also include the ASEAN.\(^\text{751}\) Other countries have also reproduced certain features of the EU model, including China, Algeria, India, Israel, Morocco and Saudi Arabia.\(^\text{752}\) One of the features in the EU that has become important is the ‘broad definition’ of a cosmetic.\(^\text{753}\) The EU has also become involved in many international collaborations. For example the International Cooperation on Cosmetic Regulation (ICCR),\(^\text{754}\) the EU-JAPAN Centre for Industrial Cooperation on Cosmetic Regulation and APRIS.\(^\text{755}\) Furthermore, the EU, with its

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\(^{745}\) See the discussions on this in Part III of comparative chapter.

\(^{746}\) There are new policies introduced in the EU Cosmetic Directive such as the amendment to prohibit the testing of animal which is culminated in the case of France v European Parliament and the Council of European Union, and the safety of nanomaterials in cosmetic products that has been discussed recently. Such developments make the EU to be considered the forefront in the cosmetic regulations.


\(^{748}\) Ibid.

\(^{749}\) Risk and Analyst Limited for the EC DG Enterprise, 'Comparative Study on the Cosmetic Legislation in the EU and other Principle markets with special Attention to so-called Borderline Products,' August 2004.

\(^{750}\) This is however subject to modifications to suit each national legislation.

\(^{751}\) Others are Mercosur and the Comunidad Andina (Andean Pact).

\(^{752}\) See the Risk and Analyst Limited, 2004, Ibid., also see McMillan, Rory and Lisansky, Steve (eds), supra.

\(^{753}\) Ibid., see next section.

\(^{754}\) The International Cooperation on Cosmetics Regulation (ICCR) is an international group of cosmetic regulatory authorities from the United States (Food and Drug Administration), Japan (Ministry of Health, Labour, and Welfare), the European Union (European Commission, DG Enterprise), and Canada (Health Canada). This multilateral framework maintains the highest level of global consumer protection, while minimizing barriers to international trade.

\(^{755}\) This seminar was a collaboration between the two countries on the commitment to start a convergence more progressively between them to inform the Japanese cosmetic industry of the new regulation on Cosmetic in the EU including on the latest development on nanomaterial.

\(^{756}\) See footnote 710 earlier.
27 countries, was the first region in the world to harmonise cosmetic regulations and this has been successful. It is therefore thought that by adopting the same regime, ASEAN with its 10 countries, could also find success.

Second, it can be submitted that the scope of the EU CD is clear and covers a well-defined product sector. For example, it has a clear and detailed definition which is the cornerstone of any system. Third, since the EU has proven a success and as the EU has carried out much research and a lot of work as far as regulation of cosmetics is concerned, it ultimately benefits ASEAN in terms of cost, to take advantage of this.

5.3 Part II : A Brief Summary for Main Substantive Elements of the ACD and Pertinent Changes to the Cosmetic Regulation in Malaysia

Introduction
Previously, it was explained how the ASEAN Cosmetic Directive was introduced in ASEAN. This part examines the effect of the ACD into being implemented in Malaysia and pertinent changes as to its cosmetic safety obligation by virtue of the ACD. From 1 January 2008, Malaysia started the implementation of the ACD as agreed in the ASEAN harmonized cosmetic regulatory scheme, which was signed on 2 September 2003. This is because the effect of the scheme was the agreement to implement the ACD into each ASEAN national country.

As previously explained, the existing legislation that had been in force in Malaysia was the Control of Drug and Cosmetic Regulation 1984. This was amended twice.\(^\text{757}\) The new requirements regarding cosmetics have not been transposed into the said regulation. Rather, the new ASEAN Cosmetic Directive requirements have been put into guidelines, namely, the Guidelines for the Control of Cosmetic Products in Malaysia 2009. This guidance was created by the Cosmetic Technical Working Group (CTWG), comprising the National Pharmaceutical Control Bureau (NPCB) and a representative from the cosmetics industry. The CTWG’s role is to put in place an effective regulatory system, taking into account the ACD, with the ultimate goal of promoting safety. It is observed that there are several notable important changes to cosmetic regulation in Malaysia through the introduction of the ACD. In fact, the ACD has actually reflected the region’s efforts to ensure the safety, efficacy and quality of

cosmetic products that are produced and marketed in ASEAN. It is not much different from Malaysia's initial aim to increase the safety.

The new system introduces product notification, which places the responsibility on cosmetics manufacturers to notify authorities of cosmetic products before they can be marketed to consumers. There is also the requirement of conducting a safety assessment of cosmetics and the product information system (PIF) by cosmetic companies. Also, another important part of the new system is the post-marketing surveillance activities by the cosmetics authority (NPCB) in ensuring the notified cosmetics in the market are in compliance with requirements so that consumer safety is ensured.

5.3.1 Pertinent Changes to Malaysian Cosmetics Regulations

5.3.1.1. Product notification replacing product registration

Prior to the introduction of the new cosmetics regulation system, cosmetic products were controlled through prior approval; i.e. the producer first had to register their product by providing details and other paperwork to be approved prior to it going into production. For example, in 2005, Malaysia's Minister of Health at the time reported that 'up to July 2005, almost 70,000 of cosmetic products were registered.' In conformity with the harmonisation of cosmetic regulations in the ASEAN, the registration system was changed to a new system which started in January 2008. Producers now only need to notify their compliance with the ACD. This is done by submitting to the NPCB such notification of compliance. Then there will be active post market surveillance conducted by the NPCB to ensure compliance. (See later section). The producer must inform the Director of Pharmaceutical Services (DPS) through the NPCB before marketing, manufacturing or importing of a cosmetic product. However what is important is that the manufacturer/company must be a lawfully registered company established under the Companies Commission of Malaysia. Also, in the Guidelines, the term manufacturer is clearly defined which is as follows;

'A company which is engaged in any process carried out in the course of making the cosmetic products. The manufacturing process includes all operations of purchase of

\footnote{This has also been reported in Asia Pacific Cosmetic and Toiletries Market Overview: Malaysia by U.S. Commercial Service of Malaysia, p. 4.}
starting materials, bulk intermediates and products, formulation and production (such as grinding, mixing, encapsulation and/or packaging), quality control, release, storage and distribution of cosmetic products and the related controls. 

Product notification is made by the cosmetics firm/manufacturer by applying online to the regulatory authority. This rationale of the notification process is to allow the NPCB to gather adequate information on the cosmetic products that are placed on the local market. A letter of authorisation from the product owner is required if the company or person notifying does not own the product. The company must be registered with Syarikat Suruhanjaya Malaysia - SSM (Malaysian Registrar of Business - ROB). The notification system emphasises the enhanced self-regulation of the industry. This means the company is fully in charge for the safety and quality of cosmetic products placed on the market. The company is responsible for following all necessary procedures fully to adhere with all the provisions in the Guidelines. Although the Guidelines aim at streamlining an effective cosmetic regulatory system without compromising consumer safety by standardising the proviso in the ACD, these Guidelines are mandatory to be followed by cosmetics manufacturers. According to the Final Report of the Tenth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) and the ASEAN Cosmetic Committee (ACC), up to May 2008, about 12,000 notifications have been received in Malaysia, despite the system just started in January the same year.

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760 The procedure is that all cosmetic products applicants are required to register for access to an online system. After having access to this system, they will be asked to properly fill in the Notification Form and to complete the process until payment submission. A notification number is given within 1-3 days after payment confirmation by authority to enable printing of the Notification Note by the applicant themselves. This Notification Note will serve as the authorisation to market, import, manufacture and wholesale cosmetic products. See the notification flow chart at the NPCB website; http://portal.bpfk.gov.my/aeimages//File/COSMETICS/Notificationprocedure_for_cosmetics.pdf (last visited 6 July 2012)

761 Notification can be made online through the NPCB website. As available from the website (http://portal.bpfk.gov.my/index.cfm?menuid=34), all applicants must register for access to the online system. After receiving access to this system, the applicant should properly fill in the Notification Form. As for imported products, it can be handled by more than one importer provided that they are authorized by the responsible company.

762 Final Report of the Tenth Meeting of the Asean Consultative Committee for Standards and Quality (ACCSQ), Asean Cosmetic Committee (ACC), 25 – 26 June 2008, Bali, Indonesia, p.4
This system of notification for cosmetics is faster than the original registration system and will in effect also shorten the product trade cycle. This eventually benefits the consumer as they will enjoy a wider choice of cosmetic products faster and is especially beneficial in terms of new technology. This system is also in place to ensure that products are of good quality and safe and to remove unsafe products from the market.

In Malaysia, as far as the new system is concerned, despite the benefits given by the notification system, it has been claimed that the notification scheme is of little benefit to product safety compared to the earlier registration system. Notification only eases the administration and management of cosmetics whilst shifting the safety burden to the manufacturers. The old system of registration meant that the safety testing was conducted by the regulatory authority and this ensured better safety in the sense that the authority was not going to tolerate any violation of its safety elements. With regard to external markets, the NPCB will give a confirmation of compliance with GMP guidelines. The pros and cons of the registration and notification system are further explained in the comparative chapter.

5.3.1.2. Safety Assessment of Cosmetic Products

The most cardinal rule of producing cosmetic products is that the cosmetics produced must be safe. In reality, cosmetics have seldom caused damage to health and because of this are not associated with much danger. Having said this, cosmetics are not always safe. The potential for long-term damage is a possibility especially given that cosmetics are frequently used over a long period of time. It is extremely important therefore, to control the ingredients to avoid this. As adopted from the EU Cosmetics Directive, the responsibility of the safety of cosmetics is the key component in producing cosmetic products in ASEAN. It also needs to be emphasised that it is not just the safety definition and safety provisions that have

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763 Anis Talib, 'Status of the ACD Implementation and Pertinent Changes to Malaysia Cosmetic Regulation,' a paper presentation at the 'Asean Cosmetic Directive Fostering Industry Compliance,' a seminar held on 19 Oct 2009, organised by National Pharmaceutical Control Bureau and The Cosmetic Toiletries and Fragrance Association of Malaysia
764 Zuraida Abdullah, 2009, supra.
765 According to information provided by enforcement officer at the National Pharmaceutical Control Bureau dated 20 April 2011.
766 Good Manufacturing Practice Guidelines is in Annex 8 of the ACD.
767 Refer to article 4 of the ACD.
768 Art 3 of the ACD
been adopted from the EU, but also the ingredients listings and the latest amendments to these, as it is specified that ‘...shall adopt the Cosmetic Ingredient Listings of the EU Cosmetic Directive including the latest amendments.’\footnote{The adoption included all of the annexes, see Article 4(2),4(3) and 4(4) of the ACD}

These ingredient listings have been reviewed and assessed by the EU scientific committee, the SCCP, and ASEAN has also established the ASEAN Cosmetic Scientific Body (ACSB)\footnote{The ACSB consists of representatives from the regulatory authorities, the industry and the academic world. At present, the ACSB is reviewing the ASEAN cosmetic ingredients (published as Handbook of Cosmetic Ingredients) as well as additions to the annexes of the Directive.} that also reviews the safety and technical data of ingredients and makes recommendations on other technical and safety issues for adoption by the ACC as well as advising the ACC of any additional requirements on the safety issues and labelling.\footnote{See next section on additional labelling requirements}

Another important element, which has been adopted from the EU Cosmetics Directive, is the safety assessment requirements. In order to achieve the safety assessment, standardisation has played an important role under the new requirements of the ACD. Compliance with the standard can provide a presumption of conformity. The ACD requires ‘an assessment of the safety of human health of the finished products, its ingredients, its chemical structure and its level of exposure.’\footnote{Article 8 of the ACD.}

The safety assessment is mandatory and must be conducted by a qualified professional defined as the ‘safety assessor’ who under article 40 of the ACD must possess ‘a qualification in a relevant field, for example, a diploma in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline and be suitably trained in safety.’

In this regard, there are guidelines specifically produced under the ACD, namely, ASEAN Guidelines for Safety Evaluation of Cosmetic Products. These Guidelines took their inspiration from the SCCP Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation.\footnote{European Commission (Health and Consumer Protection Directorate General), 'SCCNFP Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation,' 6th Revision, 2006. As discussed in the EU chapter.} In Malaysia the ACD Guidelines above have been transposed into the Guidelines of Control of Cosmetic Products, in which the safety assessment part is specifically addressed in Annex 1, part 6.

According to the Guidelines, cosmetics cannot be put on the market if a safety assessor considers that it is not safe under the ‘normal or reasonably foreseeable
conditions of use’. The safety assessor will have made recommendations which need to be adhered to. This forms part of the safety statement which if requested should be presented to safety inspectors together with the certificates of the safety assessor. Choosing a safety assessor is an important issue for the producer, not just from a legal point of view. It might also be important for other reasons, for example, company image and product liability. Clearly, risk cannot be completely eradicated, residual risk will always remain but reasonable efforts should have been made in line with current practices. There is no set approach to the safety assessment. The process differs from product to product according to the ingredient used as well as product formulation and data/information available. It must be noted that the most essential key for the safety evaluation process is to base it on the toxicological properties of its substances. In Malaysia, there are some issues regarding safety assessors. For example it has been indicated that there are very few appointed safety assessors in Malaysia, and the fact that there is a lack of infrastructure to carry out the safety assessment especially the in vitro test (in a special laboratory) complicates the safety assessment process.

5.3.1.3. Cosmetic labelling

As in most jurisdictions, labelling is also part of cosmetic safety framework in Malaysia. Here, the company or person responsible for placing the cosmetic product in the market must ensure that their cosmetic products conform with the labelling requirement; defined in Annex 1, part 7 for Cosmetic Labelling Requirements in the ACD as ‘information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets.’

As mentioned, by labelling, consumers are able to obtain information which can assist him make an informed decision regarding his purchase, for example if a consumer has any allergy with any substances, reading the label helps him avoid the adverse effect of the allergy. In Malaysia, in accordance with the ASEAN Cosmetic Directive, the Malaysian Guidelines for Control of Cosmetic specifies the procedures of cosmetic labelling, including explaining ‘name of the cosmetic

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774 As explained in the theoretical chapter.
775 According to a safety assessor in Malaysia through discussions conducted on 28 March 2011.
776 Ibid.
777 Section 8 of the Guidelines for Control of Cosmetic 2009
778 Article 6 of the ACD.
products,” immediate and outer packaging as well as the language that must be used; in English and/or Bahasa Malaysia (Malaysian national language). In 2008, in the Tenth Meeting of the ASEAN Cosmetic Committee (ACC), additional mandatory labelling requirements were added. There are the requirement to label the ingredients for four specific products; fluoride in children oral care, cosmetics containing alpha hydroxyl acid (AHA), sunscreen and hydrogen peroxide (H2O2). 

First, for fluoride in children’s oral care products, for any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. ‘for adult use only’) the following labelling is obligatory: “Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor.”

The second product that required additional labelling is alpha-hydroxy acids (AHAs) for consumer use with mandatory labelling as; ‘Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin’s sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards.’

Also for AHAs, if it is used in any sunscreen products, sunburn alert labelling is required. Third; for any sunscreen product, there is an additional labelling that is mandatory to be put, that is "Do not stay too long in the sun, even while using a sunscreen product.” The fourth product that requires added mandatory labelling is hydrogen peroxide (H2O2). It is required that products containing H2O2 and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide in Annex III part 1, are labelled as follows:

a) Oral hygiene products: Up to 0.1% of H2O2 present or released. No other limitations or requirements as well as no mandatory labelling.

779 Name of the cosmetic product means the name given to a cosmetic product, which may be an invented name, together with a trademark or the name of the manufacturer, in Section 8 of the Guidelines.

780 Immediate packaging is defined in the Guidelines as 'the container or other form of packaging immediately in contact with the cosmetic product while outer packaging means the packaging into which the immediate packaging is placed. See Section 8 of the Guidelines. The information on the label shall be in English and/or Bahasa Malaysia.

781 Tenth Meeting of the Asean Consultative Committee for Standards and Quality (ACCSQ), Asean Cosmetic Committee (ACC), 25 – 26 June 2008, Bali, Indonesia.

782 Ibid.

783 Glycolic and Lactic Acid, their common salts and their simple esters at concentrations ≤10% calculated as acid, at final formulation pH ≥3.5.
b) Tooth whitening products for application by the consumer under the supervision of a qualified dental practitioner:

c) Up to 6% of H2O2 present or released. Limitation is that supply can only through a qualified dental practitioner and not for direct sale to the general public.

There is a mandatory labelling for b), which should be as ‘Not for direct sale to the public. For supply only through a qualified dental practitioner. Read & follow the instructions and use the product accordingly. Do not use the product within two weeks prior to, or immediately after dental restoration. Not for use by pregnant women or habitual tobacco and/or alcohol users. Stop using immediately if you experience any tooth sensitivity, gum irritation, toothache, defective restorations, gingivitis, nausea etc. Store out of reach of children.’ For c, the labelling is required as; ‘Not for direct sale to the public. Only to be used by a qualified dental practitioner. Do not use the product within two weeks prior to, or immediately after dental restoration. Not for use by pregnant women or habitual tobacco and/or alcohol users. Stop using immediately in case of tooth sensitivity, gum irritation, toothache, defective restorations, gingivitis, nausea etc.’

It seems that the mandatory requirement added, as mentioned above, was done to tighten safety especially due to the fact that skin type among ASEAN people is believed to be more sensitive and therefore such labelling helps the consumers to get information so that they can exercise care when selecting products. It is presumed that such additional labelling requirements as imposed above are made because the ASEAN regulators believe that there is a lack of awareness and that if consumers are better informed they will be better protected.

v) Product information files (PIF)

It should be noted that the cosmetic company or person placing the product on the market is responsible for providing all data, certificates or any relevant safety information requested by the NPCB. In this new requirement, the PIF does not have to take the form of an extensive collection of paper records stored in a specific location or ‘a dossier.’ There are Guidelines published for helping the cosmetic company comply with labelling requirements. It is mentioned by the Guidelines

784 Guidelines for Product Information File (PIF).
that the physical location of the safety data and product information which could possibly be in electronic format can be kept anywhere, as long as the information is readily accessible on request.\textsuperscript{785} In short, a PIF is required for all notified products.

The ACD\textsuperscript{786} requires the person or companies placing a product on the market to keep the product information file ‘readily accessible to the regulatory authority of the Member State concerned at the address specified on the label.’ It is submitted that the product information required under the ACD includes the ‘safety evaluation for human health of the finished product, its ingredients, their chemical structure and level of exposure.’\textsuperscript{787} Furthermore, the company is also required to keep the existing data on undesirable effects on human health resulting from use of the cosmetic product\textsuperscript{788} and also the supporting data for the claimed benefits of the cosmetic products should be made available, to justify the nature of its effect.\textsuperscript{789}

Article 8 of the ACD states that the company or person responsible for placing the cosmetic product in the market shall keep the PIF readily accessible to the regulatory authority at the address specified on the label, which, according to the labelling requirements\textsuperscript{790} is ‘the name and address of the company or person placing the product on the local market.’ The definition of such has been given in the ‘Guidance Document on Product Notification to the Regulatory Authority’\textsuperscript{791} as ‘the local company responsible for placing the cosmetic product in the market, which may be a local manufacturer or an agent appointed by a manufacturer to market the product or the company that is responsible for bringing in the product for sale in the country, etc.’ This statement clearly refers to both a company holding an address in the local market, and to the importing company; whether they be an importer, a manufacturer or a distributor. A further recommendation is that a PIF is held for no less than three years after the product last came on the market.

\textsuperscript{785}Annex 1, part 5 for Guidelines for Product Information File (PIF).
\textsuperscript{786}In accordance with article 6 of ACD.
\textsuperscript{787}Art 7(d).
\textsuperscript{788}Art 7(e).
\textsuperscript{789}Art(7 (f).
\textsuperscript{790}Appendix II, C (e).
\textsuperscript{791}This is available in ASEAN website at http://www.aseansec.org/19014-4.pdf, (last visited 7 July 2012).
5.3.1.4. Safety and efficacy data

Another change that is pertinent in the new safety requirements is that the Product Information File (PIF) must also provide complete information on the safety evaluation and data of the finished product as well as any information relevant to effectiveness in order to support any claims made on the product. For safety evaluation, an assessment report concerning the safety for human health of the finished product based on its substances, their chemical composition and level of exposure must be signed by the safety assessor. The adverse event report in the PIF should be kept updated by the company to show the latest recorded adverse effects on consumers. In terms of product claims, the product’s efficacy assessment should be available to show its effects. This information should either come from its composition, from tests as well as from supporting data.

While the safety assessment must be fulfilled before the product notification is done, there is another interesting point, that is, every imported product from overseas, especially from Europe, Australia, and the USA, should have their safety data assessed even though it has already been made available. It is also necessary to repeat compatibility studies in the local setting for the following reasons. First, Asian people's skin tends to be more sensitive and, second, the hot and highly humid climate may alter skin properties in relation to the product. This has the potential to promote a skin sensitisation effect. It may be argued that such reassessment on products coming from overseas may fall under the category of ‘justified discrimination’ - Technical Barrier to Trade (TBT), under Article 20 of the General Agreement of Tariffs and Trade (GATT) of the World Trade Organization (WTO) on Public Health. Article 20 of the GATT allows governments ‘to step in, in order to protect human, animal or plant life or health, provided that this is not disguised protectionism. Although there are no cases of cosmetics being held under this provision, a comparison can be made with food products.’

Under the WTO, agreement has been reached on the way countries can put into practice food safety and animal and plant measures (sanitary and phytosanitary measures (SPS)). This is to give a country a guarantee that the food being consumed is of a good standard and safe. SPS measures provide the basic rules and it permits

countries setting their own standards. The measures also provide that ‘regulations must be based on science and they should be applied only to the extent necessary to protect human, animal or plant life or health.’\(^{793}\) It says that:

‘Member countries are encouraged to use international standards, guidelines and recommendations where they exist. When they do, they are unlikely to be challenged legally in a WTO dispute. However, members may use measures which result in higher standards if there is scientific justification. They can also set higher standards based on appropriate assessment of risk so long as the approach is consistent, not arbitrary.’\(^{794}\)

The provision deduces that the agreement continues to enable different countries to use different methods to inspect products as they see fit. It is thought that such reassessment is considered justified because the different weather and skin type may affect the safety. It has been indicated by a safety assessor\(^ {795}\) that there was a case where a cosmetic product from overseas had caused ‘sensitization effects’ when used by a Malaysian consumers. Here, safety of consumers should be the most important criteria and as explained in the previous section, it was the first guiding principle consideration.\(^ {796}\)

vi) Pre-market and Post-market activities
Underpinning the actions in the sphere of cosmetics safety legislation are the pre-marketing and post-marketing surveillance activities. As explained, the difference with the previous exercise on pre-marketing was that new cosmetics need to be registered before being introduced to the market - so the new implementation focuses on product notification. Further to the pre-marketing activities that had originally been in place in the existing practice, there is a new exercise that is, the principle of surveillance. It is an essential characteristic of the new safety requirements under the Cosmetic Guidelines. In light of the new safety requirements, post marketing surveillance activities are implemented with the objective of ensuring that the notified cosmetic products in the local market are in compliance

\(^{793}\)SPS measures at http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm, (last visited 10 February 2012).
\(^{794}\)Ibid.
\(^{795}\)Based on information given by a safety assessor in Malaysia on 28 March 2011
\(^{796}\)Jesus Motoomull, supra, 1998, p. 85.
with the ACD requirements. Furthermore, surveillance activities only become evident when cosmetic products that are unsafe are removed before reaching the hands of the consumer. These surveillance activities are actively conducted by the NPCB.

In this instance, the NPCB has a central role in the area of post marketing in verifying compliance through market supervision and attending the facilities of the producers. Among the post marketing activities conducted are the screening of the information or formulation of the notified cosmetic. They are also responsible for carrying out auditing, ensuring the Product Information File is in place and carrying out the safety assessment of the product.\textsuperscript{797}

In Malaysia, there is an exercise of ‘audit priority’ conducted by the NPCB. Three types of products are normally given priority: high-risk products, for example, baby products; products to be used around the eyes and mucous membranes; and, whitening products. These are among the most common cases reported, especially as many use illegal chemicals in their formulations, which is the reason why they must be closely scrutinised. If the notification holder happens to be someone who has previously been involved in a case then it is most likely that they are also prioritised.

The NPCB has further power to monitor the label of targeted products. In addition, they are also responsible to handle product complaints and product sampling. In 2009, between January and September alone, 52\textsuperscript{798} complaints were received by the NPCB. Of all the complaints, the most commonly received were related to advertising regulation, such as the ‘non-cosmetic claims,’ claims normally for medical products. The examples are a shampoo, apart from its function to cleanse hair, is also added ‘to restore hair growth/cells’, also any face cream which has a false claim ‘with fungicidal/virucidal action,’ skin lotion that is claimed ‘to improve blood circulation’ or ‘can removes scars.’ Article 9 of the Guideline for Control of Cosmetic specifically says that cosmetic products should not make claims that are regarded as medicinal in nature. There is a guidance document called ‘Cosmetic Claims Guidelines’ on examples of non-permissible claim.\textsuperscript{799}

Other example of complaints are the incomplete labelling requirements, undesirable side or adverse effects of a product, unsatisfied customer with certain

\textsuperscript{797} Article 6 of the Guidelines.
\textsuperscript{798} This information is based on an informal discussion with an officer from the NPCB dated 29 March 2011.
\textsuperscript{799} Appendix 7, Annex 1, part 8 ACD.
products, and claims substantiation.\textsuperscript{800} Such claims mostly came from consumers, but in some cases came from competitors.\textsuperscript{801} In regard to claims, a claim can be submitted formally to the NPCB by anyone if a problem is encountered with the notified product. For product sampling, products are chosen to be sampled based on the screening of the notified cosmetic products, product complaints, media surveillance, any input from the Good Manufacturing Practice (GMP) inspection or GMP status as well as from the information from other regulatory agencies such as ASEAN ALERT.\textsuperscript{802} It is reported that approximately 50\textsuperscript{803} product samples are targeted every month.\textsuperscript{804} In 2009, there were 292 targeted samples received by the NPCB, and of that number, 222\textsuperscript{805} products passed the lab test, which means that the rest of the samples failed the lab test. As far as the ASEAN Cosmetic GMP\textsuperscript{806} is concerned, auditing premises is also conducted to ensure compliance with such practice. If a product fails the then no product notification will be issued.

Apart from exercising pre-market control, post-market activities are also one of the main elements under Malaysia’s cosmetic safety regulation. These activities are conducted by the cosmetics authority, the NPCB, with the objective of ensuring the notified cosmetics in the market are in compliance with the requirements and to remove unsafe products from the market. The post-marketing activities conducted are product withdrawal and product recall and information sharing between ASEAN countries (ALERT system).\textsuperscript{807}

In the theoretical chapter, it has been explained that the use of product recalls points to another way in which legislation has impacted on product safety-risk management,\textsuperscript{808} the NPCB is given the power to initiate the product recall as far as safety of cosmetic products are concerned. The recall, (or what the EU has called withdrawal), as meant in the Guidelines, is ‘a process taken by the company or person responsible for placing the cosmetic product on the market to remove or withdraw a particular product from all channels of distribution.’\textsuperscript{809} It must be noted

\begin{itemize}
  \item \textsuperscript{800}Information given by the officer at the NPCB (29 March 201).
  \item \textsuperscript{801}Ibid.
  \item \textsuperscript{802}It is the system of information sharing between ASEAN countries, infra.
  \item \textsuperscript{803}Ibid.
  \item \textsuperscript{804}Ibid.
  \item \textsuperscript{805}Ibid.
  \item \textsuperscript{806}Ibid.
  \item \textsuperscript{807}See next section.
  \item \textsuperscript{808}See part II, chapter 2.
  \item \textsuperscript{809}Section 15 of the Guidelines for Control of Cosmetic Malaysia.
\end{itemize}
that the removal or withdrawal may be due to the discovery of adverse cosmetic effects or any critical quality defects reported that might pose danger or risk to consumers during and after distribution of the product. The purpose of a cosmetic recall is to swiftly and efficiently trace any batch of cosmetics that does not conform to the provisions in the Guidelines for Control of Cosmetic Products in Malaysia or that can be harmful to consumers.

The decision for recall is made when there is or may be a risk to the user of the cosmetic product. Recalls under the guidelines can be ‘initiated voluntarily either by the company or person responsible for placing the cosmetic product on the market or at the directive of the Director of Pharmaceutical Services (DPS).’

Concerning the statistics that involve recalls of cosmetics, between January and September 2009, the number of products cancelled or recalled amounted to 224 cases. This includes products that contained prohibited ingredients or exceeded the maximum allowable limit (205 cases), whereas the rest were adulterated products. An example of a case where there was a failure to comply with the heavy metals limit involved the use of mercury. Based on the statistics, it is quite surprising to see the number of recalls on cosmetic products over the 9 month period in 2009. The statistic denotes that for whatever reason recalls had been done; such products should not be on the market, let alone in the hands of consumers. Either such recalls were because the product posed a major health risk that might cause serious injuries or death or the recall was for a product that offered a minor risk or was substandard. The numbers should not be treated lightly.

One of the most essential elements under the post marketing system that is now in practice is the start of warning and information sharing between ASEAN countries. This is called the ASEAN alert system or known as ALERT. This system is now in place and is working properly. In 2009, between January and September, eight products were identified under the ALERT system and circulated to all ASEAN countries. These products were identified as adulterated with ‘hydroquinone’ or/and ‘tretinoin.’

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810 Section 15 of the Guidelines.
811 Zuraidah, 2009, supra.
812 See next section.
Part III: Issues, challenges and some notes of recommendations

Introduction

It is undeniable that every newly introduced system has its own teething problems. Harmonisation of any kind in fact is a challenge to any country including ASEAN states, and similarly it is not easy to transpose and implement it in each member country. Malaysia was among the first countries in ASEAN that had welcomed the harmonisation of cosmetic and had complied with the agreed time for implementation, which was 1 January 2008. Since being implemented, there are some concerns worthy of discussion. This last part examines the issues and challenges of the implementation of the newly introduced system in Malaysia. It will be concluded by discussing the challenges and some recommendations at the end of this part.

5.4.1 Issues concerning the implementation of the new ACD in Malaysia and actions taken by the NPCB

There are several issues that have raised some obstacles concerning the implementation of cosmetic regulations in Malaysia. One main concern that requires the regulators monitoring is the borderline issues of drugs and cosmetics. The determination of the classification is a very serious concern for manufacturers who may not wish to have their product rejected through the product notification. There is also the concern of consumers, who may wish to ensure that the cosmetic products in their hands are safe for their consumption. The distinction between a cosmetic and a drug is usually not determined by the ingredients included in a product formulation, generally, the intended use controls the product classification. One example is eye toner, which should be classified under pharmaceutical. It must be noted that in the definition section, a cosmetic is defined as ‘any substance or preparation intended to be placed in contact with the various external parts of the human.’ Therefore, an eye toner does not fit the definition of a cosmetic since it is meant to be put into the eyes whereas to serve as a cosmetic it must be used externally.

Another issue is the use of illegal ingredient product formulations, especially in whitening products, which are among the most reported cases. The most common
example of illegal chemicals is the use of tretinoin\textsuperscript{813} and hydroquinone\textsuperscript{814} acid in
whitening products, which the producers purposely include in the formulation to obtain quick results albeit they know such chemicals are unsafe. These chemicals are considered as scheduled poisons and are therefore regulated as pharmaceuticals. They are only allowed to be used under medical supervision and only supplied by doctors and pharmacies. In a study on the safety of hydroquinone,\textsuperscript{815} it was strongly suggested that this particular substance should be totally banned particularly in the skin cream. This is because, based on the study, that ‘the common effect was found such as white patches on the skin, particularly on the face (leukoderma with confetti-like depigmentation), and subcutaneous dark collections of pigment (exogenous ochonosis), and it was suggested that the long-term side effects are a possibility; cancer being the most likely.’\textsuperscript{816}

As mentioned earlier, whitening products are among the most popular products under the cosmetic range in ASEAN. Under the new system, whitening products are among the products which have been closely scrutinised by the NPCB.\textsuperscript{817} In this new exercise, they are regarded and treated among the ‘priority products’ to be audited by the NPCB due to the possible adulteration with the mentioned substances i.e. hydroquinone and tretinoin. On 17 May 2010, there were three beauty products recalled by the Ministry of Health Malaysia for adulteration by such chemicals.\textsuperscript{818} The Ministry of Health announced the recall and required that the sale and distribution of all the stocks cease immediately and reminded the consumers who had already purchased the products to stop using them forthwith.

\textsuperscript{813}It should be noted that in Annex II part I, tretinoin falls under the category of lists of substances which must not form of the composition of cosmetic products.
\textsuperscript{814}For hydroquinone, such substance falls under the category of lists of substances that cosmetic products must not contain except subject to restrictions and conditions laid down (Annex III Part II)-that is only 0.3% can be use but only for oxidizing colouring agent for hair dying and 0.02% for artificial nail system.
\textsuperscript{816}It was reported that hydroquinone and its metabolites can cause damage to DNA and inhibit apoptosis of mutated cells. The carcinogenic action of benzene was reported as difficult to attribute to its hydroquinone metabolite. Whereas according to the study, daily use of hydroquinone caused it to accumulate in the body as absorption into the skin was faster than excretion in the urine. Kooyers, \textit{op.cit}, 2004, p.771.
\textsuperscript{817}Other than whitening product, baby products are also regarded as ‘priority products’.
\textsuperscript{818}This ban was announced in all the mass media.
The next issue concerns the non-cosmetic claim usage by a producer over a cosmetic product. There are cases of cosmetic products that have made non-cosmetic claims. This is considered as a misleading information/label and unjustifiable product name. One example is that of a product that was claimed to be an antibacterial shower bath whereas the formulation did not contain any antibacterial agent at all. If a producer intends to make a claim, for example, 'this product is dermatologically tested,' it clearly has to be supported by concrete evidence.\textsuperscript{819}

There is another important thing that has not been understood by some producers or if understood, has been ignored,\textsuperscript{820} that they are not allowed to make unacceptable claims. The unacceptable claims are commonly observed for cosmetics in certain types of products, for instance, hair care. Examples of common unfounded claims are; 'this product eliminates dandruff permanently,' this product restores hair cells, hair loss can be arrested or reversed, and this product stimulates hair growth. In terms of skin products, common claims are that products prevent, reduce or reverse physiological changes and the degeneration of the skin due to ageing. Other skin products claim that they can remove scars, can treat cellulite or remove fat. All these claims are unacceptable under the Guidelines. To make them acceptable, the claims should be limited i.e. made less functional and more cosmetic in nature by the use of modifiers. An example of this would be a claim for removing all oil from skin. This claim could be reduced instead to: helping to remove oil from skin, managing shiny, oily skin, suitable for oily skin, or perhaps, makes skin feel less oily. In these sorts of situations, the NPCB will cancel the product notification.

There have also been occasions when labelling guidelines have not been complied with. The Guidelines for Control of Cosmetic Products\textsuperscript{821} states what is required 'to be placed on the outer packaging, or, where there is no outer packaging, on the immediate packaging of the cosmetic products.' In many cases, the non-compliance of such requirements comes from failure to list down the full ingredients, failure to put warning requirements, and some companies do have ingredients listing which differ from what have been put in the notified documents. In the case of non-

\textsuperscript{819}Please note that the issues that fall under advertising law are not covered in this thesis. See details in Chapter One under the Section: Limitation of Study.
\textsuperscript{820}Information provided during a conversation with a Cosmetic Officer in the NPCB dated 12 April 2011
\textsuperscript{821}Annex 1 Part 7 Cosmetic labelling requirement.
compliance of the labelling requirements, the NPCB will request that clarification and warning letters will be sent to the companies.

Lastly, there are also fake and counterfeit products that mostly come from neighbourhood countries and are sold much cheaper than the original products. Normally, such products can easily be identified due to the place sold. A popular product from Japan, SKII for example has only appointed certain sellers to sell the products, and such sellers normally are big companies that sell it at special counters in malls and other specified places. However, similar names and packaging are also found in many booths that also sell other products, and which are sometimes even sold by illegal immigrants. This counterfeiting issue is actually under the auspices of the Custom Office as well as Ministry of Home and Consumer Affairs, since it relates to copyright and trademark.

5.4.2 **Actions taken by the authority**

For cosmetics companies who are suspected of violating the requirements under the Cosmetic Guidelines, the NPCB has the power to reassess their product notification. In case there is any real violation, then they will be issued a cancellation of product notification. The NPCB also has the power to mandate product or batch recalls if in their opinion, a particular cosmetic is unsafe or even of a low quality. As mentioned earlier, for companies with a ‘violation history,’ if they reapply for the product notification, then they will be treated under the ‘audit priority.’

Lastly, penalties for the cosmetic violation are stated in the Control of Drugs and Cosmetic Regulations (CDCR) 1984. As far as penalties are concerned, according to the Control of Cosmetic Regulations 1984, for any offences relating to a conflict with any part of the CDCR 1984, the offenders can be fined up to RM25,000 (£5,000) or jailed for up to three years for the first offence, and fined up to RM50,000 (£10,000) or jailed up to 5 years or both for a repeated offence. The cosmetics company involved can be fined up to RM50,000 (£10,000) for the first offence and up to RM100,000 (£20,000) for a subsequent offence.

5.4.3 **Challenges for the Implementation of New Cosmetic Safety Requirements in Malaysia**

There are several challenges as to the implementation of the ACD requirements. First, free movement of cosmetics should be a positive in the ASEAN region. Here,
there is a possibility of consumers having access to substandard products that make unsubstantiated claims and advertising. Free movement also opens the door to the unauthorized importation of cosmetic products due to the easier notification process. Second is compliance with post market surveillance requirements. There is a need for the authority to develop the competency and capability to conduct the new requirements of post market surveillance activities. There is also a challenge to increase the laboratory capability and capacity to conduct the product testing to meet the increasing number of product samples. In addition, it is indicated that there is also a lack of infrastructure and services in Malaysia for product testing and safety assessments.

As far as the Product Information File is concerned, not all of the players in the cosmetic industry are able to comply with the PIF requirements without difficulty. Especially the SME industry, where the PIF requirements for safety assessments, efficacy support, product claims and advertisements as well as labelling requirements are amongst the various important issues under the PIF. Many of them are still struggling with the preparation of such documents. In certain other cases, there are also manufacturers of the imported products who refuse to provide the required documents. Similarly, there is also a lack of competent personnel for the regulators and the industry to conduct PIF auditing.

Concerning product notification, this new system involves a new procedure. However, there is a lack of knowledge concerning the notification requirements. Some of the producers, due to the easier notification process, make use of the notification system. For example, notifying a non-cosmetic product as a cosmetic (eye drop, injectable product, product for men’s sexual performance), giving an invalid manufacturer or GMP facilities that do not exist, and giving a false declaration for illegal ingredients, as well as unauthorised holders.

### 5.4.4 Some Considerations for Recommendation

**Strengthening the Post market surveillance system**

A new online system called Quest 3 has been established to fully utilize the notification information for more systematic and proactive post marketing activities. As far as PIF is concerned, there is training for auditors and competent personnel.

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822 Information provided by officer of the NPCB dated 27 March 2011.
For product sampling, there is a need to identify other criteria for targeted samples apart from the existing criteria. The industry must also be encouraged to cooperate and to provide information to the regulators, for example, in the product label/claims.

5.4.5 Enforcement
It is important to have mutual collaboration with the State Pharmacy enforcement to monitor cosmetics in the local market as well as between the enforcer and the customs to monitor product clearance at the entry points. There should also be a monitoring of cosmetic advertisements in the mass media and mass printing. A smart system should also be in place to check or verify the product status.

5.4.6 Consumer awareness
An interactive webpage for consumer education and review might be useful in order to promote awareness among consumers. Furthermore, seminars and workshops or exhibitions are also useful for the above reason. Collaboration in conducting relevant research at universities and other relevant agencies will also help promote knowledge. At the moment Malaysia has an efficient national body, known as the Standards and Industrial Research Institute of Malaysia (SIRIM). SIRIM is tasked with conducting product evaluations and certifications and developing product best practice guidelines. Its role is very much to assist the industry to make products in line with Malaysian and international standards. However, SIRIM does not have any enforcement powers. Producers submit their products for testing on a voluntary basis, there is a cost involved for receiving SIRIM certification on products. Producers gain credibility and competitive advantage by displaying SIRIM certified standard marks on their products. SIRIM does not keep records of accidents/injuries sustained in the use of cosmetics, nor does it produce mandatory standards for industry or test products prior to being placed on the market. Consumers should make a complaint if any problems arise.

5.5 Conclusion
Malaysian cosmetics regulation has undergone significant shift after the introduction of the new system. This came about from the harmonisation of cosmetics regulations in the ASEAN region. The concept of harmonisation in globalisation is an admirable
goal. Maintaining the same set of standards worldwide would benefit the cosmetics industry as well as the regulators and consumers. Although this region has just begun to implement the new directive, which was modelled on the EU Cosmetics Directive, the benefits of harmonisation are already apparent. In this chapter, it should be noted that much of the data/information of the actual procedure of implementation of the new regulation came from the insights given by several officers from the Cosmetic Unit, the enforcement officers, and the safety assessor that works in the industry. Although no formal interviews were conducted, rather, more informal discussions were had, the information gathered proved very beneficial in getting an in-depth understanding of the procedures and the system. As mentioned in the introductory chapter, the lack of materials whether written academic discussions or online sources means there is very limited information particularly addressing the adaptation of the new system into Malaysia’s cosmetics scheme.

In conclusion, undoubtedly, the alignment of cosmetics regulation encourages innovation and enhances the market growth of cosmetics. It seems that the development of cosmetics regulation in the EU countries by way of harmonisation will be followed and adopted by ASEAN although there is no single system currently in place that is perfect. The EU Cosmetics Directive however has been identified as being the best model for ASEAN. It is undeniable that there are some challenges and issues in the course of implementation of these new requirements. The issues and challenges however do not seem to override the principles of harmonisation and the benefits produced. More importantly, cosmetics harmonisation benefits consumers, in so far as safety is concerned, because of the common and standard safety assessments and the responsibility of safety now being placed on the manufacturers. Consumers also enjoy more products because of the elimination of trade barriers through free movement and cooperation between member states.
Chapter 6: Comparative Analysis of Cosmetic Safety Regulation in the EU, Malaysia and the USA

6.1 Introduction

This chapter aims to make comparisons between the jurisdictions of the EU, the USA and Malaysia as regards cosmetic regulation and draw conclusions where possible especially as to which jurisdiction has the most efficient framework for regulating the safety of cosmetic products. In all three jurisdictions, cosmetic products are subject to regulatory controls. The primary purpose of cosmetics regulation in all jurisdictions is to ensure the safety of cosmetic products and to avoid harmful effects on consumer health. A closer analysis of comparisons between these three jurisdictions demonstrates that all have recognized the importance of cosmetics safety; however, each of them has carried out its implementation in a different way.

From previous discussions, the significant differences are mainly between the EU and Malaysian systems on the one hand compared with that of the American system on the other. Both the EU and Malaysia have controls over their cosmetics safety through legislation, that is, through their Cosmetics Directives. For Malaysia, although the model for their cosmetics safety regulations is from the EU, in which similar framework had been taken especially through certain substantive elements of law and provisions adapted from the EU Cosmetic Directive, there are differences as far as procedures are concerned, for example the exercise of product notification and certain additional labelling requirements in Malaysia. Between the three, the most different regulatory framework for cosmetic is the USA. Contrary the EU and Malaysia that use predominantly public regulation, the American system has

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823 This chapter will not discuss the details of regulation in each jurisdiction as they have already been discussed in Chapter 3, 4 and 5 respectively. It will only discuss the substances of comparison in relation to the main principles of product safety regulation.


825 Note that although the model for Malaysian cosmetic system is from the EU, Malaysia has certain differences especially in regards to the procedures and activities including some additional requirements.

826 Discussions of the national chapters are the EU, the USA and Malaysia in chapter 3, chapter 4 and chapter 5 respectively.

827 Being a member of ASEAN, Malaysia has modelled its law on the EU Cosmetic Directive which has been transposed into the Guidelines for Control of Cosmetic 2009. See Part I, ch. 5

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depended heavily on the cosmetics industry to regulate itself in ensuring cosmetics safety and has fostered a self regulatory\textsuperscript{828} regime for their cosmetic products. While the EU’s cosmetic safety structure is considered extensive, the USA’s system has been termed the most ‘liberal.’\textsuperscript{829}

This chapter is divided into three parts. Part I briefly recapitulates the substantive principles of cosmetic regulatory frameworks in the EU, the USA and Malaysia followed by analyses of substances of similarities and differences of the three jurisdictions compared. The comparison is made by using the important elements in the product safety principles without giving details as they have already been mentioned in the previous chapters. For Malaysia, after adopting the EU Cosmetic Directive,\textsuperscript{830} it has totally moved from prior approval (cosmetic registration) to cosmetic products notification. Therefore, in Part II, the impact of the changes is discussed including the advantages and the disadvantages of both registration and notification systems. The last part; Part III concludes the discussion in this chapter by analysing which jurisdiction between the three has the most efficient system for regulating the safety of cosmetic products using the product safety important criteria mentioned in the theoretical chapter, that are the information regulation, safety responsibility, the pre-market as well as the post market control obligations.

6.2 Part I: Principles details of regulatory frameworks for cosmetic products in the EU, the USA and Malaysia

Introduction

It is generally accepted that the two regions, the EU and the USA, are at the vanguard of today’s globalized economies.\textsuperscript{831} This is evidenced from the fact that both are among the models used by other countries. Bach and Newman\textsuperscript{832} analyse the governance of both these leading markets from the standpoint of their structural

\textsuperscript{828}J. Thomas and Donegan, ‘Fifty Years and Cosmetic Safety: A Government and Industry Partnership,’ \textit{Food and Drug Law Journal}, 151, 1995, p. 2. Japan for example, has experienced the most dramatic change to its cosmetic regulation as it ‘deregulated’ from prior approval system for cosmetic starting from 1 April 2001. See See L. Gagliardi and S. Dorato, 2007, p. 14. Malaysian cosmetic system has also changed. See the Malaysian chapter and is explained in the next section.

\textsuperscript{829}See L. Gagliardi and S. Dorato, \textit{op.cit.}, 2007, p. 3.

\textsuperscript{830}By virtue of being an ASEAN member.

\textsuperscript{831}Please refer to each national chapter for the estimation of the market for cosmetics.

\textsuperscript{832}Bach and Newman, \textit{supra}.
capacity and power in the cosmetic and pharmaceutical sector. They through their observation, the empirical evidence demonstrates that domestic regulatory institutions of each jurisdiction had systematically formed international market regulation for cosmetics. They also suggest that between the EU and the USA, it is the EU that has tenaciously ‘shaped’ global rules for cosmetics. Many of the current cosmetic product frameworks have been adapted from the EU by other countries. For example, a study on the comparative cosmetics legislation found that around 30 countries have adopted the EU lists which also include the ASEAN. Other countries have also reproduced certain elements from the EU model. One of the elements in the EU that has become important is the ‘broad definition’ of a cosmetic. The EU, through its Cosmetics Directive, has also implemented the ingredients lists system which consists of approved, restricted and prohibited ingredients. The aim of the Directive is mainly to guarantee product safety for the consumer, while facilitating the cosmetics trade within the EU.

In the USA, by contrast with the other two compared jurisdictions, its cosmetics industry is based on self-regulation. The Federal Food Drug and Cosmetic Act (FD&C Act) dated 1938 is the oldest law in the world on cosmetics, and it is still applicable. The Food and Drug Agency or FDA, an agency under the purview of USA’s Department of Health and Human Services is given the mandate to enforce the said law. The self-regulation in the USA cosmetic regulation means that it has relied on industry-led ingredient review. Many programmes developed by cosmetics industry, particularly the CFTA involve voluntary aspects to assure the FDA, the cosmetics industry and the public that cosmetic products are safe and properly

833 Ibid., p. 1.
834 Bach, David and L. Newman, Abraham, p. 1
835 Ibid.
837 This is however subject to modifications to suit each national legislation.
838 Others are Mercosur and the Comunidad Andina (Andean Pact).
840 Ibid., see next section.
labelled.\footnote{Peter Barton Hutt, 2000, \textit{supra}, p. 29.} Hutt\footnote{\textit{Ibid.}, p. 29.} for example has claimed that ‘[n]o industry in the history of this country has ever made a greater commitment to self-regulation or has been more successful in achieving it than the U.S.A cosmetic industry.’

Apart from that, the USA cosmetic system is also supported by the Color Additive regulations,\footnote{The Color Additive Amendment Dated 1960. \textit{The Color Additive Amendments of 1960.} See N. Barrows, L. Lipman, and J. Bailey, ‘Color Additive: FDA’s Regulatory Process and Historical Perspectives,’ \textit{Food Safety Magazine}, October/November 2003.} which are considered particularly stringent.\footnote{In fact, most countries that specifically regulate cosmetic colours have used the USA regulations as a source. For example, Japan. See further G. Murphy, Emalee, Regulation of Cosmetic Colours in Other Countries, \textit{Food Drug Cosmetic Law Journal}, Volume 37, 1982, pp. 163-171.} To the present day, colour additives are subject to this strict system. They must adhere to the requirements of approval the USA law.\footnote{Sec. 601(e) FD&C	extsuperscript{a}A, 21 U.S. Code 361(e). Also available at \url{http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/ucm110032.htm}, (last accessed 10 December 2011).} Failure to meet the requirements causes cosmetics to become adulterated.\footnote{See L. Gagliardi and S. Dorato, \textit{supra}, 2007, p. 12.} In addition to approval, a number of colour additives must be batch certified by FDA if they are to be used in cosmetics in the USA.\footnote{\textit{Ibid.}} Also, there is also a requirement to batch certify all colour additives for identification as specified in the Code of Federal Regulation (CFR).\footnote{See earlier section.} It is noted that colour additives are only allowed to be used for the intended uses stated in the said regulations. In addition, there are certain limitations on the use of certain colours, such as the maximum permitted concentration in the finished product.

While cosmetics in the EU are considered under an extensive regulation,\footnote{The Campaign for Safe Cosmetic has made such claims in the USA, see \url{http://safecosmetics.org/article.php?list=type&type=30} (Last accessed 7 January 2012). The Campaign for Safe Cosmetics is a coalition effort launched in 2004 to protect the health of consumers and workers by securing the corporate, regulatory and legislative reforms necessary to eliminate dangerous chemicals from cosmetics and personal care products.} it has been claimed that cosmetics in the USA are ‘among the least regulated products on the market’\footnote{David and Abraham, \textit{op.cit.}, 2008, p. 2.} due to the fact that the development of this industry has relied on industry-led ingredient review. Whereas the situation is different with regards to the regulation involving pharmaceuticals, in which the USA has long been dominant;\footnote{\textit{Ibid.}} the USA regulatory framework of cosmetic has been argued as ‘paled as compared to
the parallel case of pharmaceutical.' Some writers have even asserted that the FDA requires more stringent standards. However, despite such calls no changes have been made to the American system. Greff for example, states that ‘cosmetic portions of the FD&CA have remained essentially unchanged.’

Malaysia has the newest regulation on cosmetics compared to the two other jurisdictions, having only been implemented its new law on the 1st of January 2008. Previously, it was under the Control of Drugs and Cosmetic Regulations (CDCR) dated 1984, which required prior approval through licence application before marketing cosmetic products. In 2007, the CDCR was amended to accommodate the changes that have been made with the introduction of the ACD. The new requirements in the ACD have been put into Guidelines for Control of Cosmetic Product. Earlier, in 2003 ASEAN and its member countries have sought to harmonise cosmetics regulation. This led to the introduction of this new regulation, called the ASEAN Cosmetic Directive (ACD) in 2003. The most significant fact is that the ACD is based on the EU Cosmetics Directive of 1976. To help implement this Directive into Malaysian law, the Cosmetic Technical Working Group (CTWG), consisting of the National Pharmaceutical Control Bureau (NPCB) as well as representatives from the cosmetic industry prepared the Guidelines for Control of Cosmetic Products. Having implemented the new law, the most pertinent change is the introduction of product notification which replaces the product registration. This is among the main point of difference with the EU system, despite adapting from the EU substantive framework. However, as newly implemented, challenges remain such as the lack of infrastructure especially for product testing and safety assessment.

Although it might appear from the discussions that the USA, through its self-regulatory cosmetics system has lesser controls compared to that of the EU and Malaysia, it is imperative to mention that perhaps the additional roles are played by

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855 Among of the examples are Termini and Tresler, supra, 2008.  
856 A. Greff, supra, 1996.  
857 Ibid., p. 244.  
858 This Regulation is in exercise of the powers conferred by section 28 (1) of the Sale of Food and Drugs Ordinance 1952 being the main Act.  
859 According to Control of Drugs and Cosmetic Act 1984 (of Malaysia), under Part III, Section 7(i) specified that no person shall manufacture, sell, supply, import, possess for sale any product unless the product is a registered product; and the person holds the appropriate license required and issued under these Regulations.  
860 Part III (Registration & Licensing), Section 7-25 of Control of Drugs and Cosmetic Regulations 1984.  
861 Directive 76/768/EEC.  
862 Anis Talib, 2009, supra.
product liability.\textsuperscript{863} For example, it has been suggested that Americans are more litigious than the Europeans.\textsuperscript{864} They have been known for their large number of cases in product liability claims, including in cosmetic lawsuits. For example, it was reported that in 2008,\textsuperscript{865} lawsuits were filed against several personal care companies in the USA whose products allegedly contained several carcinogenic substances without any reasonable warning.\textsuperscript{866} The other important reason for product liability litigation in the USA is the amount of damages which are considerably higher. This in itself acts as a magnet for litigants, because of this, the risks of producing dangerous cosmetic are sometimes mitigated by adverse publicity.\textsuperscript{867}

6.3 Comparisons between the three different systems concerning cosmetic safety regulation

6.3.1 Similarities
All the three jurisdictions share some similarities. The similarities are, the responsibility for determining safety of cosmetics is placed on cosmetics manufacturers, no prior approval is required for cosmetics in all three jurisdictions, and lastly all of the jurisdictions impose post-marketing surveillance activities. These are explained below.

6.3.1.1. The safety provision and the responsibility for producing safe cosmetics on the manufacturer/producer
In all mentioned jurisdictions, all cosmetic products put on the market are required to be safe for consumption. The Directives of the EU and ASEAN (Malaysia) have a specific provision on producing only safe cosmetics.\textsuperscript{868} Both Directives clearly outline the basic level of safety required for producing cosmetic products. In the USA,

\textsuperscript{863}It has been explained that consumers in the USA enjoy more autonomy compared to consumers in many other jurisdictions. See the USA chapter.

\textsuperscript{864}Howells, 2000, supra, p. 307.


\textsuperscript{866}Note that cosmetic manufacturers in the USA have duty to warn for products not substantiated their safety. See USA chapter and part II of this chapter.


\textsuperscript{868}Article 2 of the EU Cosmetic Directive and Article 3 of the ASEAN Cosmetic Directive.
despite the fact that such specific provision is absent, such obligation actually exist; in that the obligation has resulted from the *de facto* effect of the prohibitions of ‘adulterated’ or ‘misbranded.’ Although it can be argued that the adulterated and misbranded provisions are much broader and are not specifically aimed at ensuring the production of safe cosmetics. These implied provisions, therefore, can be said to be an incentive for producing only safe cosmetics, because failure to verify their safety may mean that the products are adulterated misbranded.

Apart from the safety obligation, all jurisdictions compared in this study recognise the responsibility for the safety of cosmetic products should lie with manufacturers. It is the guiding principle, since, being the manufacturer they are the party that deals with the product. The EU and Malaysia requires the manufacturers to take into consideration the general toxicology properties of the substances used as well as their chemical structure and their level of exposure. That means the manufacturers in both jurisdictions are responsible for the safety of their product from the very beginning (that is during its formulation), until it has become a finished product; taking into particular consideration all the necessary safety requirements. Not only the manufacturer who must be responsible, but also the first importer in the EU market as well as the marketer.

Regarding the responsibility for safety of cosmetic, similar to the EU and Malaysia, the cosmetics manufacturers in the USA are also obliged to verify the safety of their products before they are marketed or otherwise, as explained, the product can be adulterated or misbranded. A safety responsibility principle is also evident in Malaysia, where the company or person placing the product on the market must be responsible for ensuring the safety, quality, performance or efficacy of the cosmetic product released to the consumer on the market as well as ensuring that the products fulfils all the requirements in the regulations.

6.3.1.2. No requirement for prior approval

In general, the three jurisdictions have less rigorous pre-market control for cosmetics compared to some other product types that represent more serious risks to consumers, for example, for pharmaceutical products. Thus, cosmetic products in

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869 Through control ingredients and safety assessments.
870 Unless there is a warning given as noted above.
871 Article 4.2 of the Guidelines for Control of Cosmetic Products.
all the three jurisdictions are not required to obtain approval from the regulatory authority before being placed on the market. For all the jurisdictions, since cosmetic are not subject to prior approval procedure, no license is required before producing cosmetics, unlike drugs products. The three jurisdictions seem to agree that such a procedure should not be placed on cosmetics since it could be too onerous given that the risks are not as high as those pharmaceuticals products. Nevertheless, other pre-market tools are implemented to control what may be placed on the market. The next part discusses the detailed differences in how these are carried out.

6.3.1.3. Post-marketing surveillance activities are also part of the cosmetics safety framework in the EU, the USA and Malaysia

As explained in the theoretical chapter, safety reassurance does not end when a product is placed in the marketplace. Once a product is launched, the cosmetics producer/manufacturer needs to engage in active monitoring of the consumer's experience to confirm product safety. In this regard, cosmetic and personal care product manufacturers are required to conduct post-marketing surveillance activities for the identification of potential safety issues related to their marketed cosmetics.

All of the compared jurisdictions in this study provide post-market tools to supplement the pre-market tools. Gagliardi and Dorato argued that such systems could help to identify the adverse effects arising from the use of cosmetics. Although adverse effect/adverse reactions that are both serious and unexpected are quite rare for cosmetic and personal care products, they still need to be addressed and cannot be underestimated. For example, a report by the National Register for Adverse Effect from Cosmetic Products held that the Register received 96 notifications related to daily personal care products during the first two years including products that are usually low-risk cosmetics such as skin moisturisers.

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872 It was however practised under the old cosmetic system in Malaysia. See further discussions in Part III.
873 For example product notification is exercised in Malaysian current system. The EU Cosmetic Regulation also includes the notification system when it is implemented in July 2013.
874 L. Gagliardi and S. Dorato, supra, 2007, p. 5.
All of the three jurisdictions apply post-marketing surveillance in order to check the compliance with each of the legislations. These monitoring activities are carried out by the regulatory authority. Mostly these activities involve product withdrawal and product recall, enforcement and issuing penalties for violations. However, the way in which post-marketing surveillance is implemented is different in each jurisdiction, which is explained in the next section.

6.3.2 Differences
The different approaches to regulating cosmetics in all the three jurisdictions are mainly connected to divergent definitions of cosmetics, labelling requirements and lists of ingredients that are permitted, restricted or banned. Apart from these differences, other distinctions can be drawn concerning pre-market control and post-market activities, in which each jurisdiction has its own way of conducting business as discussed below.

6.3.2.1. The definition of cosmetics and issues arising from the definitions
The borderline products subject is one of the main issues that is raised in regards to cosmetic legislation in the EU/ Malaysia and the USA. The EU/Malaysia and the USA have quite similar approaches for determining which products are subject to cosmetics regulation but their categorisation of products differs particularly with regard to drawing the borderline as to whether a product is a cosmetic or a drug. The importance of having these differences in the definitions determined in each jurisdiction will determine which products fall under which regulations. In all jurisdictions, the category of ‘cosmetic product’ has potentially common characteristics with the pharmaceutical products. It is important to note that the EU/Malaysia’s product categorisations are based on the formulation of the product, such as the existence of certain active ingredients and the intended main (cosmetic) function. Such product determination exercises have been confirmed by case law of the European Court of Justice which has also supported the fact that a product cannot fall within the definition of two product categories at the same time.

876 L. Gagliardi and S. Dorato, op.cit., 2007, p. 4.
877 Note that a similar definition is applied in Malaysia.
878 Active ingredients are ingredients used in making the pharmaceutical products. It is however is not defined in the Cosmetic Directive.
The main difference with regard to the definition of cosmetics in the USA is that the EU/Malaysia does not recognise this USA category of ‘cosmetics that are also drugs.’ Also, the EU/Malaysia does not have an additional category for drugs in which some cosmetics may fall, that exists in the USA which has ‘over-the-counter’ drug category, known as OTC. This fact is given as a reason why certain cosmetics can be very close to being drugs, depending on the ingredients used or the advertising claims made for them. Having examined the OTC-cosmetic categories, it seems the OTC classification, which stands between cosmetics and drugs - less strict than drugs and more stringent than cosmetics, can however make up for the less strict system for cosmetics. It might be the case that although some potent cosmetics do not fall within cosmetics requirements because of the leniency of the system - by the mere fact of having the OTC category, other much more potent cosmetics do not slip through and can be subject to OTC requirements. For products classified as both cosmetics and drugs, they must fulfil the requirements of regulations for both product categories. Products that do not fulfil the definition of cosmetics, often based on claims made rather than composition, are regulated as drugs. These are categorized between cosmetics and drug and can be sold without prescription.

The main implication of having different definitions in the different jurisdictions is that some products regarded as cosmetics in the EU have the status of OTC drugs in the USA. Such differences are complicated by the fact that manufacturers in each jurisdiction might want to export their products to each others’ jurisdictions, however the difference in rules could create difficulties, and would certainly increase costs. This of course creates trade barriers which is contrary to, and defeats the purpose of, the principle of harmonisation of cosmetics regulations which has become more important in the cosmetics sector.

6.3.2.2. Pre-market control for cosmetics
a) Controls over ingredients and the safety assessment
Ensuring the safety of cosmetic products is the most crucial task and has been seen as one of the most important determinants for the safety of cosmetic products in the EU and Malaysia. The rationale behind this exercise is that it is possible to assess their safety by considering and examining the relevant toxicity of their

879 It is explicitly mentioned in Article 2 of the EU and ASEAN Directives.
However, it is only implicit in the USA’s cosmetics system in that it is done through a prohibition of ‘adulterated and misbranded’ cosmetics. Although it has been explained that the USA’s provisions on adulterated and misbranded products can carry *de facto* effects, it has however been claimed that very little litigation has resulted from such provisions. As such, this might be linked back to the fact that the power of the regulator is weak, which is logical given cosmetics fall under a voluntary programme. Also, with regards to the ‘duty to warn’ provision, in a way it may look like a warning to the consumer about the product, however it does not warn the consumers about the potential harm the products can bring – as there is no testing assessment. This is confusing to the consumer considering the fact that many of them are still mistakenly under the impression that the FDA test the safety of cosmetics. Consumers deserve better protection than simply being alerted that most cosmetics are not tested for safety. Also, it has been claimed by some academics that based on the FDA’s prior (poor) enforcement record, the cosmetics industry will probably not adhere to the warning requirements and the FDA rarely enforce them.

Therefore, from the exercise, it is thought that the USA control over ingredients and safety assessments is not as extensive as in the EU. In the EU/Malaysia, ingredients that form part of cosmetics regulation must fall under the approved list before use in a cosmetic formulation and that no ingredients that fall under the prohibited list are allowed to be used. It is noteworthy that there have been 1328 ingredients banned in the EU/Malaysia from cosmetic formulations compared to not more than 11 banned by the USA. This shows the lack of stringent checks or regulatory intervention in cosmetic control. Producers in the USA can use many more substances in the composition of cosmetics, but can also theoretically export their goods containing substances that are not banned in the USA but are banned in the EU/Malaysia. Legislators in the EU/Malaysia will of course not allow such products to enter their markets if they do not adhere to their safety requirements.

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880 ICCR Guidance on Principles for Cosmetic Products Safety Assessment, p. 3.
881 See the definition in the earlier section.
882 Page and Blackburn, *supra*.
884 This exercise has also been subject to critics, discussed in the USA chapter.
885 Annex II of the Directive
b) Evaluation of the ingredients

All of the jurisdictions compared in this study have their cosmetics scientific committee for reviewing the ingredients in the cosmetics formulations. However, the main difference lies in the fact that the scientific committee in the EU (the SCCP) and ASEAN/Malaysia (the ACSB)\(^{886}\) are given the responsibility to review contents while the USA’s CIR\(^{887}\) only does this voluntarily with no official status. Being a third party body consisting of scientific experts,\(^{888}\) it must however be noted that, CIR has been funded by the CTFA\(^{889}\) although in terms of operation, it works separately from the CTFA and the cosmetics industry in the USA. Although this activity is voluntary and has no official status, it is claimed that it has considerable influence on the formulation decisions of cosmetic manufacturers. It was suggested that manufacturers generally take these conclusions as definitive in formulating their products.\(^{890}\)

On the other hand, consumer advocacy groups have criticised the CIR by arguing that the FDA was too dependent on CIR for cosmetics safety assessment, which is complex due to the fact that what constitutes safety substantiation has not been defined by the FDA. Therefore, ‘[w]hat is acceptable as safe is up to each manufacturer conducting safety testing.’\(^{891}\)

In contrast to the EU which has the General Product Safety Directive, (which serves as a safety net when there is any violation of safety that has not been covered by the cosmetic directive) the USA however, does not have any similar regulation. The Consumer Product Safety Act (CPSA) 1972, which gave Consumer Product Safety Commission (CPSC) power to regulate ‘consumer products’ however, specifically excludes cosmetics from its jurisdiction.\(^{892}\) Although this has been subjected to severe criticism including the accusation that the FDA dealt too leniently with violators, and that it is less stringent compared to the CPSC, this situation still

\(^{886}\)ASEAN Cosmetic Scientific Body.

\(^{887}\)Cosmetic Ingredient Review.

\(^{888}\)The panels consist of expert from variety of scientific disciplines including dermatology, pharmacology, chemistry, and toxicology. Government agencies, cosmetic companies, and consumer publicly nominate these experts to be part of the CIR panel.

\(^{889}\)It is the leading national trade association representing the global cosmetic and personal care products industry in the USA.

\(^{890}\)B. Fernandez de Córdova Manent and E.F. Gonzalez Abellan, op.cit., 2007, p. 36.


\(^{892}\)Section 3 (H) (15 U.S.C. 2052). As explained, cosmetics are under the FDA’s jurisdiction together with foods and drugs products.
remains in place to this day. For Malaysia, although there are no specific regulations on product safety, the Consumer Protection Act 1999 has provided in Part III the provision for product safety, which means that, in case any consumer products, including cosmetics, failure to ‘observe a reasonable standard of safety,’ then the responsible person/body will be penalised.

c) Safety assessment
Another important element in the context of cosmetics safety is the implementation of safety assessments by a safety assessor. This exercise is required in the EU and Malaysian cosmetics systems but not in the USA. This exercise is beneficial because it validates product safety after the evaluation by a scientific committee that the ingredients are safe, it is also reliable because the person conducting the assessment, according to both Directives, must be a qualified person. A safety assessor does not just certify that a product is safe, according to his expert knowledge in the field, but he certifies that a product is safe according to ‘reasonably foreseeable conditions of use.’ The absence of the requirement of a safety assessment to be conducted by a safety assessor is yet another deficiency in the USA cosmetics system, compared to those of the EU and Malaysia. For Malaysia, although this requirement has also been part of the system, the lack of safety assessors to conduct testing has been regarded as one of the main problems in carrying out the new system, thus affecting its efficiency.

d) Prohibition of dangerous substances
Lastly, in terms of the control of ingredients, another distinct way that the EU Cosmetics Directive ensures safety (which has been followed by Malaysia) is the prohibition of dangerous ingredients under a chemical safety classification grouped as CMR substances. It controls the categorisation, packaging and labelling of dangerous chemical placed on the market in the Member States of the EU/ASEAN. Also, there is a list of materials that can be used and marketed in the EU/ASEAN (Malaysia) in restricted amounts, which includes cosmetic products. Many of these

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893 Specifically dealt with in chapter 5.
894 Act 599 of Malaysia.
895 Section 19 (4) of part III, CPA.
896 Section 145 of part XIV, CPA.
897 As listed in categories 1, 2 and 3 under Annex I to Council Directive 67/548/EEC.
substances have been added in Annex II of both the EU/ASEAN Directives. It is noted that this provision is totally absent in the USA. As explained in the theoretical chapter, ingredient control is one of the main elements for determining the safety of products that mostly contain chemicals. Allowing cosmetics companies to put/use any ingredients in their composition suggests that the regulator is not serious about protecting the safety of cosmetic products. This is one of the most serious criticisms levelled against the USA system, even by some American academics.\footnote{Among of the examples are A. Greff, Jacqueline, ‘Regulation of Cosmetics that are also Drugs,’ 1996, \textit{Food and Drug Law Journal}, Volume 51, p. 243. Also, see R. Johnson, ‘Not in My Make-Up: The Need for Enhanced Pre-market Regulatory Authority over Cosmetics in light of Increased Usage over Engineered Nanoparticles,’ 26 \textit{Journal of Contemporary Health Law and Policy}, 82, 2009, pp. 82-214} It is also relevant to mention that there is a strong chance that because dangerous substances that have been proven to be dangerous are not prohibited for use in cosmetics, producers may still use these substances without being caught if they happen to cause no noticeable effects.

e) Cosmetics labelling

Cosmetic labelling is very important in regard to the safety of cosmetics in that these requirements will help to protect consumers from health hazards and misleading conduct as well as to assist them in making informed decisions concerning product purchase. This is one of the most important elements under the principles of product safety. Labelling of cosmetics is required in all jurisdictions compared in this study, and most importantly this includes the ingredients declaration. Each jurisdiction has published its own guidelines for the labelling of cosmetics. However, labelling of cosmetics in the USA is subject to rather different requirements than in the EU. Whereas the EU Directive is quite strict with respect to the form of cosmetics packaging, the USA law imposes more lax formatting requirements on information displayed on cosmetics labels.\footnote{15 U.S.C.§ 52 (1982)} Unlike the EU Directive which makes it an obligation for a cosmetic to be labelled with the ‘expiry date’/’use by’ date, or ‘period-after opening’, the USA does not require such information to be displayed. This has also been the subject of much criticism, because without this information, no indication is given to the consumer about when they should stop using a product. It may be the case that some cosmetics products are not likely to cause harm after a period of time, but there will be others that cause severe reactions. Detection of
expiration will come down to luck and deciding, in a rather unscientific way, whether a product appears to be in date by touch or sight.

Also, as previously mentioned, there is also another important distinct requirement concerning labelling of warning statements which is added to protect consumer safety, that is, a warning statement that should be put by cosmetics manufacturer for products that are not safety tested that should be placed conspicuously on the display panel.900 With regard to this warning statement, it has been argued that, although the FDA does not have any authority to require the cosmetics companies to conduct mandatory safety testing, the negative effect of the warning on the perceptions of consumers may compel the companies to carry out assessment of safety for cosmetics.901 It is undeniable that the warning, is important; however, linking back to the theoretical safety chapter, it is reasonable to suggest that some consumers have the tendency to ignore them. As such, information stating that no safety testing has been carried out might not be as useful as it should be.

In Malaysia, labelling of cosmetics set out in the ASEAN Cosmetic Directive Labelling Requirements is quite similar from that of the EU.902 However, Malaysia903 has put additional labelling requirements. For example the requirement to label the ingredients for four specific products; fluoride in children oral care, cosmetics containing alpha hydroxyl acid (AHA), sunscreen and hydrogen peroxide (H2O2).904 It seems that the mandatory requirement added, as mentioned above, was done to tighten safety especially due to the fact that skin type among ASEAN people is believed to be more sensitive and therefore such labelling helps the consumers to get information so that they can exercise care when selecting products. Therefore, it can be observed that labelling in Malaysia is much stricter compared to the EU and the USA. In this context, it is thought that such additional mandatory labelling required is necessary and relevant to ensure the consumer is better protected.

900It says: ‘Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the display panel: Warning: The Safety of this product has not been determined.’21 C.F.R. § 740.10 (1975).
902Under Appendix II of the ASEAN Cosmetic Directive.
903ASEAN meeting in 10th ACC Meeting 10th ACC Meeting (25-26 June 2008).
904See details in Malaysian chapter.
In short, based on the above analysis, it seems that the criticisms levied against the lax USA system have some basis in fact. It must be mentioned that pre-market obligations, as explained in the theoretical chapter are very significant in controlling what may be used in cosmetics. Despite their general safety norms, consumers are better protected by the exercise of pre-market controls.

6.3.2.3. Post-marketing activities

Under the principles of product safety regulation, post-marketing control is essential as it enables the producer to be informed of the risks that appear from the use of the cosmetic, as well as to take appropriate action when there is any possibility of danger resulting from such use in the long term. In fact, post marketing activities are as important as pre-marketing ones. For cosmetic products in the EU/Malaysia legislation, they have authority to require a post-marketing surveillance system to ensure the provisions specified in both Cosmetics Directives are complied with.

One of the important elements in the EU and Malaysia with regards to post-marketing that is very distinct from the USA system of post-marketing is the keeping and updating of relevant information about the product including safety assessment details using the PIF system. Although it can be covered under pre-marketing, this exercise is also covered under post marketing so as to compare it to any equivalent in the USA. In the USA, similar to the practice in the EU, the post-marketing surveillance is also one of the important activities that is conducted. However, there is no similar practice in terms of the technical documentation concerning the cosmetic product’s design and labelling, including a risk assessment of cosmetic products or any equivalent to PIF in the EU. Although no similar system is required in the USA, the closest to it is the Voluntary Cosmetic Registration Program (VCRP). The VCRP acts with the cooperation of the cosmetics industry in order to administer the cosmetics regulation. In the absence of a PIF system, this system is used to encourage cosmetics companies to provide information about any raw materials and ingredients used in their compositions, as well as any adverse effects caused by their products. The system is voluntary which means that cosmetics producers can choose to register but there is no obligation to do so. Up to August 2011, 1168

905 21 C.F.R. § 710.
cosmetics firms have filed 38,450 active products with the VCRP. This is a high figure but it is believed that there are many more firms which are not registered. It is also thought that unless such a programme is made mandatory, it will be impossible to gauge how many cosmetics establishments are operating in the USA, as well as how many substances are being used in their formulations.

In addition to the system regulating information, product or batch marking is another measure to enable cosmetic producers to be informed of risks. As explained in the theoretical chapter, batch marking helps identify and trace the products and producers easily. Indeed, product or batch marking can facilitate the effective product recall of a specific identifiable batch, thereby avoiding recalling other items unnecessarily. Through this, if a problem should arise, it will limit the quantities of the products that have to be recalled or ‘held’ in stock pending further investigation. Batch marking has been practised in cosmetics in the EU/Malaysia. However, it is not a mandatory practice in the USA, except for cosmetics that use colour additives. It must be remembered, that not all cosmetics use colour additives. Cosmetics with colour shades, lipstick or eye shadow for example use colour additive, but these are not used in simple moisturisers or shaving cream. It is thought that it is better to have batch marking in all cosmetics and not just coloured products.

Withdraw, recall, enforcement

Under the post marketing surveillance, recall of cosmetics is carried out in all of the three jurisdictions. In the EU and Malaysia however, withdrawal is also carried out. The differences between recall and withdrawal have been mentioned earlier. In the USA, inspection is carried out to ensure the safety of cosmetics and determine whether cosmetics are adulterated or misbranded which could identify possible health risks and other violations of the law. If the authority finds any case that could possibly be linked to a health risk, then there is a practice in place of issuing warning letters (and close-out letters) by the FDA. Regarding inspection, it is perhaps relevant

910As defined in section 601 and 602 of the FDC &Act. See Part II for the general discussions, and the details discussions in the USA chapter.
to recapitulate that according to critics, despite the FDA having such power, cosmetics facilities are not frequently inspected due to limited resources.\textsuperscript{911}

Unlike the EU and Malaysia that can require a recall, in the USA, as far as cosmetic products are concerned, recalls\textsuperscript{912} of cosmetics are only voluntary actions carried out by manufacturers or distributors to remove products that pose a danger and those that are found to be deceptive, from the marketplace. Here, FDA classifies a firm’s action as recall (as opposed to withdrawal) when it determines that the product hazards represent a violation of the FD&CA. What is the most difference is that, as opposed to the EU/Malaysia, the FDA has no authority to mandate recalls of cosmetics but it does monitor companies that conduct a product recall and may request a recall if the firm is not willing to remove a dangerous product from the market without the FDA’s request. This is different from the practice of the Consumer Product Safety Commission (CPSC) who can require recalls of potentially dangerous products. \textsuperscript{913} As mentioned in the previous section, this is one of the greatest criticisms against the FDA – that it deals too leniently with violators, and is much less stringent compared to the CPSC. This is still the case to this day.

The implementation of post marketing activities in Malaysia is carried out in a different way. Despite many similarities with the EU practice, some aspects of post marketing activities are different, or rather, have been added to suit the operation of enforcement procedure and practice. In addition to withdrawal and recall which are carried out in a similar way with the EU, several additional elements of post market surveillance activities are conducted by the authority under the banner of ‘targeted product monitoring.’ The targeted products, as has been explained, are products with unjustifiable claims, such as whitening products and products with a ‘previous non-compliant’ history. These strict additional post market surveillance activities conducted by the cosmetics authority are understandable and justifiable because these are among the major problems that are caused by many cosmetics manufacturers in Malaysia. Despite the lack of resources at the disposal of the ASEAN/Malaysian regulator, an extra effort has been made to administer this

\textsuperscript{911}Ibid.
\textsuperscript{912}Recalls are addressed in Title 21 of the Code of Federal Regulations (CFR), through section 7.40, section 7.59.
particular product monitoring. This is because these products pose greater danger to consumers and because the result of not doing so would be catastrophic for consumer safety. It is therefore felt that the benefits of conducting this exercise are greater than the costs.

Lastly, the EU and Malaysia have a system ensuring that information about hazardous/unsafe products is used to remove them from the market and/or recall them from consumers anywhere in Europe/ASEAN and that this information is swiftly disseminated between member states, so that proper action can be taken everywhere. The RAPEX system (for the EU) and ALERT system (for ASEAN/Malaysia) have been useful and work properly as they issue specific warnings about any problems with cosmetics and allow for information sharing between member countries. There is however no evidence that this exercise is practised in the USA.

6.4 Part II: Pros and cons of cosmetics registration (prior approval) and cosmetics notification in Malaysia.

In the theoretical chapter, it was explained the elements of pre-marketing obligations which included prior approval. It was further concluded\textsuperscript{914} that prior approval is not suitable for cosmetics due to the nature of such products - that they are not usually associated with extreme risks. In chapter 5, it has been explained how Malaysia has moved to replace its cosmetic safety framework by following the EU. Although the same principles and regulatory framework for cosmetic safety has been applied, their implementation is different. One of the main differences is the product notification which has been introduced in Malaysia for cosmetics before they are marketed and sold to the consumers while there is no formal notification system in the current EU Cosmetics Directive.\textsuperscript{915} The new system of product notification means the old system of cosmetic registration is no longer applicable. The Guidelines specify that the cosmetic company or person responsible for placing a cosmetic product in the local market must make product notification prior to product manufacture or importation. The rationale behind the notification system is to allow the Malaysian

\textsuperscript{914}Part II and III of the theoretical chapter.
\textsuperscript{915}This system however is being formally introduced in the EU Cosmetic Regulation, see discussions in the EU chapter.
cosmetic authority\textsuperscript{916} to collect sufficient data on the cosmetic products that are placed in the local market.\textsuperscript{917} This exercise demarcates the differences from the EU, in its the current cosmetics safety obligation. This is however applicable in the EU Cosmetic Regulation which is replacing the Directive.

The idea therefore relates to why such an exercise has been introduced in Malaysia and what is the rationale behind the introduction. Prior approval as explained in the theoretical chapter involves a process in which the manufacturer of a product must obtain a license and must register their products before they are released on the market to be sold to the consumers. It is the strongest form of intervention by the public authority and is normally limited to certain consumer products. It must be noted that this burdensome requirement can only be justified where there are strong grounds to believe that products may pose unacceptable risks. As mentioned earlier, this type of control could be used not only to preserve minimum standards of quality but also to limit competition.\textsuperscript{918} However, it tends to be restricted only to some sectors (such as pharmaceuticals) and does not normally apply to general consumer products including cosmetics.

Cosmetics in Malaysia had previously been under this type of control. It has been identified that such a system has restricted cosmetics in the sense that registration involved a lengthy procedure and difficult process. As it has been argued that\textsuperscript{919} prior approval is required on such products as they can pose extreme risks, cosmetics however are ‘among the safest’ products and normally do not pose extreme risks although there are still some cases involving cosmetics. In addition, as far as the registration system is concerned, the burden of safety lies on the regulatory authority as they will have to review and approve applications by the cosmetics firms.

As the registration system has now been replaced by the notification system, the most important element is the shift in responsibility for safety to the cosmetics manufacturers/operators. Now the burden of safety for the regulatory authority is reduced to merely approving the application supported by the safety assessment and proper labelling and other requirements in the Guidelines/ASEAN Cosmetics Directive. This system of notification for cosmetics is faster than the original

\textsuperscript{916} The National Pharmaceutical Control Bureau.
\textsuperscript{917} Section 1.1.
\textsuperscript{918} Ogus, supra., 2004, pp. 235-238.
\textsuperscript{919} Ibid.
registration system and will in effect also shorten the product trade cycle. This eventually benefits the consumer as they will enjoy a wider choice of cosmetic products faster and is especially beneficial in terms of new technology. This system is also in place to ensure that products are of good quality and safe and to remove unsafe products from the market.

Although the regulatory authority where has had its safety responsibilities reduced, they have however been given a mandate to conduct stricter post-marketing activities such as screening of information/formulation of notified cosmetics, auditing the Product Information File (PIF), monitoring labels of targeted products, handling product complaints, product sampling. In Malaysia, as far as the new system is concerned, despite the benefits given by the notification system, it has been claimed that the notification scheme is of little benefit to product safety compared to the earlier registration system. Notification only eases the administration and management of cosmetics whilst shifting the safety burden to the manufacturers. The old system of registration meant that the safety testing was conducted by the regulatory authority and this ensured better safety in the sense that the authority was not going to tolerate any violation of its safety elements.

It is also very relevant to note that, in the EU, the existing EU Directive does not have such requirements. However, the new EU Cosmetics Regulation which will be implemented in June 2013 has introduced the Cosmetic Product Notification Portal (CPNP) in 2012. This is the online notification system established for purpose of the implementation of the Cosmetics Regulation. It is also important to note that the fact that a product has been successfully notified through the CPNP, it does not necessarily mean that the product in question fulfils all the requirements of the Regulation. As this is yet to be implemented, it is not known how efficient the system will be.

In conclusion, as the system of cosmetics notification is now being implemented in Malaysia, it has certainly been shown to have some problems—specifically that it does not contribute much to safety as compared to the old system.
of registration. However, to return to a system of registration would mean more hassle and a greater burden being placed on the authority to carry out a process of checks that are not necessary for products that are normally not associated with extreme risks such as cosmetics.

The EU seems to recognise the benefit of having a formal notification system thus it has been introduced as a requirement into its cosmetic system. This notification exercise has been included in the 2009 introduction of the Regulation; however the Portal has only just been introduced in 2012. Although it is believed that such system has long been considered in the EU, (in fact maybe even before ASEAN/Malaysia started the system), the fact that it has been successfully implemented and has helped ASEAN/Malaysia to achieve a more efficient cosmetic system has convinced the EU to also use it in its system.

6.5 Conclusion: Which jurisdiction has the most efficient system for regulating/controlling the safety for cosmetic product? (Public regulation v self-regulation)

From the previous discussions, the similarity between the compared legislations regarding cosmetic products, i.e. those in force in the EU and Malaysia and that of the USA concerning cosmetic ingredients lies in the fact that prior approval is not required, and thus, full responsibility for the safety of products, which depends mainly on the ingredients used, falls on the manufacturer. Earlier, Chapter Two has already discussed the significance and benefits of pre-market practice in cosmetic safety regulation without the prior approval which, among others, is the avoidance of time-consuming and expensive pre-market licensing/registration of products, as well as more efficient administration of the safety regulation. The different national approaches to regulating cosmetics in all the three jurisdictions are connected to divergent cosmetic definitions, labelling requirements and lists of ingredients that are permitted, restricted or banned. Apart from these differences, other distinctions can be made by considering the pre-market control and pre-market activities, in which each authority has its own way of conducting business. Authorities carry out pre-market tools in order to ensure compliance with the legislation.

925 L. Gagliardi and S. Dorato, supra, 2007, p. 4.
In terms of the major difference between these three regulatory systems it can be seen that while both the EU and Malaysia maintain lists of prohibited and restricted substances, together with positive lists for colouring agents, preservatives and UV filters, in the USA there are no positive lists for cosmetic ingredients (except for colouring agents) and the list for prohibited ingredients is much fewer than in the other two jurisdictions. 926 The lists in the EU/Malaysia and those in the USA are sometimes not identical and some ingredients that are prohibited or restricted in one are permitted in the other. For example, waterproof mascara by Cover Girl brand which contained ingredients called ‘petroleum distillates’ and by-oil products are banned in the EU/Malaysia while allowed in the USA.927 Furthermore, in some cases the authorized content for the same permitted ingredient differs from one jurisdiction to the other. Finally, products considered as cosmetics in the EU, are considered as OTC drugs in the USA. These product categories need pre-market approval by the competent authority and obey different regulations to cosmetics. Besides, in the case of OTC drugs in the USA, the FDA has published different monographs that compile specific data regarding these types of products with regard to the ingredients allowed and their maximum content.

Between the three jurisdictions, it is observed that the EU has the most efficient system of safety of cosmetic, as compared to the other two. This is due to the fact that there are three layers or safety elements to the safety assurance in the EU: first, the legislation itself that requires cosmetics to be safe. Second, there is the professional safety assessor who personally signs to say the cosmetic product is safe. Third, there is the control by authorities checking on products placed on the market. Although Malaysia adopts the same regulation and similar to the EU, which have the three layers safety system of cosmetic, it lacks infrastructure and resources as this new regulation has only been implemented in 2008. In comparison the USA, although having the oldest law on cosmetics, gives the FDA’s only limited statutory powers to regulate cosmetics, cosmetics are largely subject to a voluntary compliance system.

It must be noted however that in USA, this role is possibly played by civil liability. Cosmetic companies are encouraged to register voluntarily their facilities and products. They are also encouraged to voluntarily report adverse product

926 See part II of this chapter. The EU has 1328 lists of prohibited substances while the USA only banned not more than 11.
experiences. However, proponents of increased cosmetic regulation argue that participation in this voluntary compliance system is low. In addition, critics contend that the Cosmetic Ingredient Review (CIR), an industry-funded expert panel established to conduct safety assessments of cosmetic products, has only reviewed 11 percent of cosmetic ingredients.\footnote{Environmental Working Group Cosmetics Petition, note 234.} It was stated that in USA, ‘requirement for cosmetics are substantially less extensive and complex than requirements for foods, drugs, or medical devices.’\footnote{A. Greff, op.cit., 1996, p. 248} Not only has the self-policing nature of cosmetics law been subject to much criticism from outside government, but the FDA itself has also admitted its weaknesses. For example in 1978, it the FDA Former Chief Counsel for Food and Cosmetic noted; ‘the existing law has some weaknesses ... one of them being that the FDA does not have general authority to obtain manufacturers’ records and safety related data.’\footnote{Margaret Gillhooley, ‘Federal Regulation of Cosmetic: An Overview’, Food Drug Cosmetic Law Journal, 33, 1978, p. 232.}

Although the voluntary programs/system of cosmetic had always been the source of criticism, they are argued by others to be a symbol of cooperation. It has been commented that ‘this approach has been successful in obtaining information that the FDA desires to have and it has been successful for the industry in that it has stalled for a time the urgency for new cosmetic laws. ...this voluntary arrangement to work so well.’\footnote{William J. Skinner, ‘Regulatory Update on Cosmetic in the United States,’ Food Drug and Law Journal, 34, 1979, pp. 490-500.} On the other hand, critics slated voluntary programs that fail to promote industry cooperation saying that ‘a voluntary program is just that and no member of industry has to cooperate.’\footnote{Sarah H. Newman, Cosmetic Regulations, Food Drug Cosmetic Law Journal, 29, 1974, pp. 83 -87.}

It was mentioned in the earlier discussions\footnote{See Part 1 of Chapter 4 (USA chapter).} that cosmetics in the USA that have not been tested must use the ‘not tested warning.’ It was argued however, that, this warning label actually does not protect consumers sufficiently. For example, Page and Blackburn\footnote{Page and Blackburn, supra., p. 808.} contend that the weakness of the warning is in its language, in that, instead of warning about the potential harm that might occur, the warning serve only as an advice that the product has been tested its safety.\footnote{Ibid.}
In comparing between the systems, the EU system has been regarded as ‘generally more restrictive’\(^{936}\) than the USA system of regulating cosmetics. In the EU, the cosmetic manufacturers need to show a heavier burden that their products are safe. This is due to the ban of certain chemical substances\(^{937}\) which have been proven by scientific studies to be dangerous for human health. The SCCP which has been mandated with the responsibility to review cosmetic ingredients has for example highlighted its opinion that if such dangerous substances are present in a cosmetic product either from its natural ingredients, or gained during the manufacturing process, it must be shown that the product does not pose a threat to consumers’ health.\(^{938}\)

In addition, the amendments and technical adaptations in the EU that have been made several times which mainly show the EU has exercised greater control over the cosmetic safety and the ban on substances shows its control over dangerous chemical ingredients with the aim of protecting the safety of consumers as well as the environment.\(^{939}\) Also, even though prior approval is not required for cosmetics, cosmetic manufacturers are obliged to keep a safety report file (PIF), which also includes the adverse effect data, if any. This is however not a mandatory requirement for cosmetic manufacturers in the USA. The ban in the EU of the dangerous substances has demonstrated the fact that it has reinforced the concern for cosmetic safety perspective at the global stage, and its approach has been followed by other countries. This ban is hoped to encourage the USA to change its system to regulate cosmetics more effectively\(^{940}\) as it one of the most important ways of protecting the consumers from dangerous substances. Until recently, there is no sign of this happening yet. Given the fact that the EU has mandated full ingredients to be declared, together with the expiration dates, the ingredients functions, precautions to be observed, and batch numbers, the EU is noted as having a more detailed and extensive labelling requirements as compared to the USA. Lastly, the

\(^{937}\)As explained in earlier section.
\(^{939}\)For example, REACH regulation has been introduced in 2003 in the EU.
\(^{940}\)Hearn, supra, at note 170.
formation of cosmetic database in the EU provides easy access to consumer about more information they use.

Based on the above analysis, it is observed that the public regulation system of cosmetic safety exercised in the EU is more extensive than the USA system. The USA has relied on several elements to complement the lax in its system; they are the implicit safety obligation resulted from the adulterated and misbranded provisions, the duty to warn obligation for products not verified of their safety as well as the OTC categories which can be said to make up for fewer restrictions on cosmetics. Also, it must be remembered that, in terms of product liability and cosmetics cases claims, the USA have a more proactive and developed system of litigation. Product liability claims provide an incentive for producers to produce safer cosmetics. Those mentioned elements might be the reasons why, despite the lax system of regulating cosmetics by the authority, they do not intend to change the system. It can also be summarised that the Malaysia’s approach of regulation of safety of cosmetic is very close to the EU model and in that it follows all the safety principles in the EU Cosmetics Directive, for example the control of ingredients, the safety assessments and also labelling requirements. There are also some slight differences or additional requirements which have been added to suit the condition in Malaysia and in ASEAN as a whole; such as product notification and some additional labelling requirements. Though it still lacks infrastructure and resources, the continuous coordination and cooperation with the EU through APRIS program is thought to help ASEAN/Malaysia in order to achieve a safer and efficient cosmetic system. The USA model, although it is undeniable that its system has been a model for other countries, has been operating in a totally different environment to that experienced in Malaysia, thus producing different effects which are very unlikely to occur in Malaysia. Product liability in the USA which is believed to act as an incentive to produce safer cosmetics is not suitable for the Malaysian cosmetics environment particularly taking into consideration the lack of awareness of the consumer and also the cosmetics producers. Moreover, such a system allows problems to surface before rectifying

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941 This has been discussed in Malaysian chapter. APRIS or the ASEAN-EU Programme for Regional Integration Support is a programme to assists ASEAN in strengthening the post-market surveillance by providing technical assistance and training in respect of product safety and efficacy the drafting of Product Information Files and product liability for national regulatory authority and the cosmetic industry.
them. Thus for a developing country like Malaysia, based on the above reasons there is much less to be learnt from the American system.
Chapter 7: Regulation of Nanotechnology in Cosmetics

7.1 Introduction: A New Emerging Technology and Its Application in Cosmetic Products

Nanotechnology is now no longer an alien term, and is commonly found in many daily products from anti-bacterial fabrics, sunscreen to protect skin from the SPF, as well as products like the memory and computing elements of the latest and highest end computers.\textsuperscript{942} Nanotechnology has been claimed as a new revolution in technology and a significant economic development for the twenty-first century.\textsuperscript{943} The development of nanotechnology promises wide-ranging benefits on a global scale; from medical advances, to more effective use of energy resources, next generation electronics and even improvements in water quality.\textsuperscript{944} As both a science and application, nanotechnology is on the verge of creating a global revolution for many industries. Consumer products containing nanomaterials have been and continue to enter the market at a steady pace. A report by Lux Research in 2006 stated that in 2005 in excess of $32 billion worth of products were sold that contained a nanotechnological element. This figure had doubled from the previous year. The report forecast that by 2014, 15\% of global manufacturing would be nanoproducts ($2.6 trillion).\textsuperscript{945}

As of today, nanotechnology has become a very active area of research which is rapidly developing in the industrial sectors and spreading to almost every field of science and engineering, and has also reached consumer products, including cosmetics and other personal care products. As mentioned, there has been much research and development on nanostructured materials and nanotechnology in the USA, the EU as well as Asian countries such as Japan, Taiwan and Korea. This technology has become of enormous scientific and commercial interest because of its rapid development to academic institutions, governmental laboratories, and industries. It is, therefore not surprising that nanotechnology is expected to grow to a

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{942} Shatkin, Jo Anne, \textit{Nanotechnology: Health and Environment Risks}, CRC Press, 2008, p. xiii
\item \textsuperscript{943} Graeme, Hodge, Bowman, Diana, Ludlow, Karinne (editors), \textit{New Global Frontiers in Regulation: The Age of Technology}, 2007, Edward Elgar, p. 3
\item \textsuperscript{944} Ibid.
\item \textsuperscript{945} Ibid.
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multibillion\textsuperscript{946} industry and will become the most dominant technology. In addition, it provides an area of knowledge that promises greater prospects in various areas such as manufacturing, energy, health care, and others. Given the potentially immense commercial and societal benefits that may come from nanotechnology, it is likely that nanomaterials, and products and applications containing them, will be widely produced and used. One of the obvious examples is that it is now being used in cosmetics, such as in sunscreen products. Despite the hype that has heralded its potential and recognised it at the highest scientific levels, nanotechnology brings new and heightened risks that have not been fully grasped. An environmental agency, Friend of the Earth expresses their concern about preliminary scientific research that suggest nanomaterials can be toxic to human tissue and cell, such as resulting in ‘increased oxidative stress, inflammatory cytokine production, DNA mutation and even cell death.’\textsuperscript{947}

Concerns about the safety of certain nanomaterials used in cosmetic are not new. In 2004, the UK’s Royal Society\textsuperscript{948} and Royal Academy of Engineering first raised questions about the safety of nanocosmetics.\textsuperscript{949} They asserted that because of the potentially toxic nature\textsuperscript{950} of nanomaterials, they should be treated as new chemicals and assessed accordingly.\textsuperscript{951} Due to this they believed that testing on ingredients in the form of nanoparticles should be carried out before they are used in consumer products.\textsuperscript{952} In 2006, a list of 116 products (cosmetics and personal care products) claiming to use nanomaterials has been compiled from internet sites in the report ‘Nanomaterials, Sunscreens and Cosmetics: Small Ingredients, Big Risks’.\textsuperscript{953} It is believed that the list is continually being added to.

The type of legislation suitable for these new materials is very topical because of the heightened concern over their safety. As far as the regulation is concerned, at

\textsuperscript{946}For example, according to Lux Research, the nanotechnology industry is expected to grow to $2.6 trillion in manufactured goods by the year 2014. See The Nanotech Report, 4th Edition, New York, NY: Lux Research Inc., 2006, p. iii.

\textsuperscript{947}Friends of the Earth, ‘Nanomaterials: Sunscreen and Cosmetics: Small Ingredients, Big Risks,’ 2006, p. 2

\textsuperscript{948}The Royal Society is the oldest scientific academy in continuous existence.

\textsuperscript{949}The Royal Society and The Royal Academy of Engineering, ‘Nanoscience and Nanotechnologies: Opportunities and Uncertainties,’ 2004. This report was commissioned by the UK Government.

\textsuperscript{950}Nanotoxicity is a specific new scientific discipline of study; that is the study of the toxicity in nanomaterials. See C. Sahu, Saura and A. Casciano, Daniel, Nanotoxicity: From In-Vivo and In-Vitro Model to Health Risks, 2009, John Wiley and Son Inc.

\textsuperscript{951}P95 Recommendation 10, The Royal Academy of Engineering United Kingdom, 2004, ‘Nanoscience and Nanotechnologies.’ Available at http://www.royalsoc.ac.uk

\textsuperscript{952}P95 Recommendation 12(i), Ibid.

\textsuperscript{953}Friends of the Earth, 2006, Ibid.
the moment, the only specific regulation on nanomaterials is the EU Cosmetics Regulation,\footnote{Regulation 1223/2009. Discussed in the EU chapter.} which was introduced in July 2009. The EU Cosmetics Regulation contains specific reference to nanomaterials. It is the first piece of legislation that has made an attempt at defining nanomaterials, although it has wisely accepted that this definition will evolve.\footnote{European Commission, 2008h: art. 2 §§ (1)(k); 2(3).} It is also the first piece of legislation that treats them as separate entities and specifies requirements for nanoproducts to follow. This includes the appropriate way for them to be labelled and for information about them to be submitted. This differs from the American treatment of nanomaterials, and in fact other emerging technologies, that continue to be regulated under existing regulation. However, it must be noted that the Regulation is not due to be implemented until 2013, which makes the existing EU Cosmetics Directive still applicable.\footnote{http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm (last assessed 10 May 2012). For more discussions on the new regulation, see the last part of this chapter (part iii)}

The earlier part of this thesis, chapter 2, included discussions on the theory of safety regulation in relation to the regulation of cosmetic products. In understanding the discussion of product safety, and specifically cosmetic safety, it is important to provide a case study of this emerging new technology. Therefore it is imperative to highlight that the discussion does not go beyond the issues of safety and regulation. This chapter explores the respective fields of the regulation of nanotechnology in cosmetics in light of the safety and the risk it represents, and will try to determine the best adaptive regulatory framework for nanotechnology.

This chapter is divided into three parts, Part I seeks to provide an understanding of nanotechnology. In this part, it is observed that definitions of nanotechnology are varied, however for the purposes of this chapter; it will be explained in general rather than scientific. For some overly important terminologies, the meanings are explained in the footnotes. Part I also examines the use of nanomaterials in cosmetic products, their claimed benefits as well as risks including the nanotoxicity issues that are concerned with the use of nanomaterials in cosmetic products. As there is still uncertainty about the safety of nanomaterials in cosmetics, it is imperative to rely on the law and regulation to provide an answer. Part II discusses the best way of regulating nanotechnology in cosmetics, whether they
should be regarded as a part of cosmetics and regulated as a ‘traditional’ cosmetic. Within this it should not be forgotten that they remain the subject of considerable research as their safety has not been ascertained. The precautionary principle is also analysed in this part. As pre-marketing and post-marketing controls are regulatory instruments to use in any safety regulation, they too are discussed thoroughly. Part III examines the approach of the regulation of nanotechnology in cosmetics by the three chosen jurisdictions (the USA, the EU and Malaysia). As mentioned, it is evidenced that the EU and the USA are at the forefront as far as nanotechnology development, be it in terms of research or its applications. A contrast to this can be found in a developing country like Malaysia. Although the shift towards nanotechnology is evident in terms of the development of technology, it is still at an early stage.

7.2 Part I: Understanding nanotechnology and its application in cosmetics

Introduction

It is noted that considerable research has been done and funding has been spent in this emerging field. In fact, it is acknowledged as being among the biggest investments made, especially in some developed countries. The European Commission\(^\text{958}\) reported that the EU had invested significant financial resources at a comparable level to the USA and Japan.\(^\text{959}\) However, while the research and literature on nanotechnology is increasing and becoming of greater concern, it is still poorly understood. A Which? Survey carried out in 2007 showed that 61% of those surveyed were unaware of nanotechnology and its use.\(^\text{960}\) The result of the survey also held that six in ten adults had not heard of the term ‘nanotechnology’ and even of the people that had heard of nanotechnology, they were unclear about what it is.\(^\text{961}\)

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957 Traditional cosmetics, in this regard, means the original cosmetics that are used to alter the appearance of its users, such as lipstick or skin cream.
960 This survey is conducted in November 2007 by Which? Which involve a sample of 2091 adults (16+) between 14th-18th November 2011 using face-to-face omnibus survey. Following the survey, Which? undertook an additional research project with consumers that are called ‘Citizens’ Panel. The primary objectives were to explore consumer perceptions and understanding of nanotechnologies and to investigate the implications of nanotechnologies for all consumers-from consumer points of view.
7.2.1 Definitions of Nanotechnology

Nano comes from a Greek word that means ‘dwarf.’ It signifies the smallness of the size. While conceptually nanotechnology is defined by this scale; that is by its smallness, there has only been slight agreement on a universally accepted definition of nanotechnology.\textsuperscript{962} This is best illustrated in the variation of definitions given in the literature. Aitken \textit{et al.} \textsuperscript{963} define nanotechnology as ‘[a] broad interdisciplinary area of research, development and industrial activity which has been growing rapidly worldwide over the past decade. It is a multidisciplinary grouping of physical, chemical, biological, engineering and concepts in which the defining characteristic is one of size.’\textsuperscript{964} In the USA, the National Nanotechnology Initiative (NNI)\textsuperscript{965} has been established in 2001 with a view to coordinating nanotechnology research in the country. It defines nanotechnology;

‘[a]s research and technology development at the atomic, molecular, or macro-molecular levels in the length scale of approximately the 1- to 100-nanometer (nm) range creating and using structures, devices and systems that have novel properties and functions because of their small things sense and/or intermediate size the ability to control or manipulate on the atomic scale.’\textsuperscript{966}

Graeme \textit{et al.}\textsuperscript{967} gathered the examples of different definitions for nanotechnology, which have been categorised into five common characteristics. First, is the size that is from around 100 nm down to less than 0.1 nm. Second, is the range of technologies that is the imaging, measuring, and modelling and manipulation of matter. Third, is the multi-disciplinary areas, including for instance, physical, chemical and biological, with each being purposefully ‘engineered.’ Fourth, is the size dependant novel properties and functions, and lastly the control and purposeful

\textsuperscript{964}Ibid, p. v
\textsuperscript{965}The NNI serves as the central point of cooperation for all Federal agencies engaged in nanotechnology research, bringing together the expertise needed to advance this broad and complex field. See http://www.nano.gov/about-nni (last assessed 12 April 2011)
\textsuperscript{966}At http://www.nanop.gov/nanotech-101/what/definition (last accessed 20 September 2012)
\textsuperscript{967}G. Hodge, D. Bowman, K. Ludlow, 2007, Edward Elgar, p. 10
manipulation of matter at the atomic scale. Fifth, is the control and purposeful manipulation of matter at the atomic scale.968

In summary, nanotechnology can be seen as the manipulation of the essential components found in nature. The outcomes signify cooperation of many disciplines such as chemistry, biotechnology, physics, engineering ‘towards studying assemblies of atoms and molecules.’969 It seems that definitional matters are not simple. It is undeniable that people from the science background possibly have no problem in understanding the term correctly. However, it must be highlighted that most people are laymen, which means they might perceive this new emerging substance differently. Likewise, companies also perceive nanotechnology differently. For example, a survey was conducted by a consumer association in the UK, Which? on 67 cosmetics970 companies (both larger brands and SMEs) about their use of nanotechnology, the benefits they perceived it brought and how they ensured product safety.971 Although they received a very poor response,972 the survey indicated that certain brands cautiously restricted their use of nanomaterials973 while other companies used a more diverse range of nanomaterials due to their claimed benefits.

7.2.2 Nanotechnology and Its Application in Cosmetics (nano-cosmetics)

Currently, many cosmetic manufacturers use nanomaterials in their products. According to Brumfiel974 the cosmetic sector has been a leading area for the commercialization of nano-products. Nano-cosmetics are present in many skin creams – especially sunscreen, as well as hair care products. One of the brands that is well-known for using nanotechnology in their products is L’Oreal. It was reported to rank sixth in the USA in the number of nanotech related product patented.975 From the 1970s L’Oreal has been patenting Niosomes. These have been used in its

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972 With only 17 getting back, and of these, just eight were willing to give information about how they use nanotechnology.
973 For example, to nano emulsions and UV filters in sunscreens

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liposome-based anti-ageing products (creams, lotions and gels).\textsuperscript{976} Liposomes have also been used as nanomaterials by Christian Dior in its cosmetics, for example, in its Capture collection.\textsuperscript{977} Liposomes are used in cosmetic applications for ‘transdermal delivery and their use will result in an increase in the concentration of active agents such as vitamins A, E and CoQ10 in the epidermis with no risk of acute or chronic toxicity’.\textsuperscript{978}

According to Mu and Sprando,\textsuperscript{979} their research shows that the primary advantage of using nanoparticle formulations in drug delivery systems in cosmetic products is because they ‘improve the stability of various cosmetic ingredients like unsaturated fatty acids, vitamins, or antioxidants encapsulated within the nanoparticle.’\textsuperscript{980} In addition, it is used to ‘enhance penetration of certain ingredients, such as vitamins and other antioxidants, and may help increase the efficacy and tolerance of UV filters on the skin surface.’ Particle size is another benefit of nanotechnology, if we take the example of sunscreen the smaller particles mean that when applied it doesn’t leave a noticeable white mark as it used to.\textsuperscript{981}

Another example is Dendrimers,\textsuperscript{982} which are ‘unimolecular, monodisperse, micellar nanostructures with a well-defined, regularly branched symmetrical structure and the high density of functional end groups at their periphery’. These have been tested for use in drugs and cosmetics. Solid lipid nanoparticles (SLN)\textsuperscript{983}

\textsuperscript{976}Niosomes, non-ionic surfactant vesicles, are now widely studied as an alternative to liposomes. Ibid. These vesicles appear to be similar in terms of their physical properties to liposomes, being prepared in the same way and, under a variety of conditions, forming unilamellar or multilamellar structures, see Yoshioka et al., supra.

\textsuperscript{977}Liposomes, prepared from a variety of natural and synthetic phospholipids, are being considered as drug-carrying structures or vesicles. See Fang, Jia-You and Hong, Chi-Tzong and Chiu, Wen-Tand Wang, Ying-Yue, ‘Effect of Liposomes and Niosomes on Skin Permeation af Enoxacin,’ International Journal of Pharmaceutics, 219, 2001, pp 61-72.

\textsuperscript{978}Ibid.

\textsuperscript{979}Op.cit., at p. 1746

\textsuperscript{980}Op.cit.

\textsuperscript{981}It is suggested that UV filters used in sunscreen produced in nano form became clear than white when compared to their larger from. See Which?, 2008, p. 1

\textsuperscript{982}Dendrimers are hyper-branched polymers that have many interesting abilities. Dendrimers could be used, for example, as drug or gene carriers, contrast agents, sensors for different metal ions, and in developing innovation technology. See J. Steven Rutt, ‘Dendrimers and Nanotechnology: A Patent Explosion,’ a paper presented at the National Nanotechnology Initiative Conference, Washington DC, April 29, 2002

\textsuperscript{983}Solid lipid nanoparticles (SLN) introduced in 1991 represent an alternative carrier system to traditional colloidal carriers, such as emulsions, liposomes and polymeric micro- and nanoparticles. SLN combine advantages of the traditional systems but avoid some of their major disadvantages. See Sylvia A. Wissing, RH Muller, ‘Cosmetic Applications for Solid Lipid Nanoparticles(SLN),’ International Journal Pharmaceutics, 254, 2003, pp. 65-68. Also for reference see Muller RH, Mader K and Gohla S, ‘Solid Lipid Nanoparticles (SLN) for Controlled Drug Delivery- A Review of the State of Art,’ European Journal of Pharm Biopharm, 2000 July, 50(1), pp. 161-177
and nanostructured lipid carriers (NLC)\textsuperscript{984} also lend themselves well to topical application, not least because they provide “controlled release” to many cosmetic ingredients.\textsuperscript{985} Lipid nanoparticles have also been shown to help with skin conditions such as eczema, skin mycosis, psoriasis and acne. Zinc oxide (ZnO)\textsuperscript{986} and titanium dioxide (TiO2)\textsuperscript{987} nanoparticles have become popular in sunscreens because they keep UV filtration and absorption properties but at the same time do not leave a white cast on the skin. Some types of ZnO and TiO2 products have been shown to have increased sun protection factor (SPF).

Despite the fact that nanotechnology is widely used as they offered solutions to many industries, there is also another vital question, that is, how safe is it for human consumption? The use of nanoparticles in cosmetics products, in sunscreen for example, has raised some controversy, in that, recent scientific debate is focused on the ability of nanoparticles contained in topical lotions to penetrate the outer skin, layer and enter the bloodstream.\textsuperscript{988} While in other research\textsuperscript{989} it is noted that ‘studies carried out to date have reached no agreement as to whether nanoparticles can, in fact, be absorbed via the skin.’\textsuperscript{990} Balbus \textit{et. al.}\textsuperscript{991} concludes that:

‘[t]hese novel properties may pose new risks to workers, consumers, the public and the environment. The few data now available give cause for concern: Some nanoparticles appear to have potential to damage skin, brain, and lung tissues, or be mobile or persistent in the environment, or to kill microorganisms.’

In the EU, an estimate in 2006 by the EC asserted that nanoparticles formed part of 5% of cosmetic products.\textsuperscript{992} As time goes by, the number of cosmetic products containing nanoparticles is most likely increasing as they are claimed to give many

\textsuperscript{984} According to Radtke, Magdalene and B. Sauto, Eliana and H. Muller, Rainer, 'Nanostructured Lipid Carriers: A Novel Generation of Solid Lipid Drug Carriers,' \textit{Pharmaceutical Technology Europe}, 2005, 17(4) pp. 45-50, nanostructured lipid carriers are ‘a new type of delivery system offering improved performance in terms of drug loading and long-term stability with the ability to form highly concentrated dispersions.’

\textsuperscript{985} For example coenzyme Q10, ascorbyl palmitate, tocopherol (vitamin E) and retinol (vitamin A), over a prolonged period of time, exhibiting low toxicity and low cytotoxicity. \textit{Ibid.}

\textsuperscript{986} \textit{Op.cit}

\textsuperscript{987} \textit{Op.cit}

\textsuperscript{988} See Balbus, J.M., R. Denison, K. Florini and S. Walsh, 'Getting Nanotechnology Right The First Time,' \textit{Issues in Science and Technology}, Summer 2005, pp. 65-71

\textsuperscript{989} Swiss Re, Nanotechnology: Small Matter, Many Unknown, 2004, Geneva, p.18

\textsuperscript{990} Balbus, 2005, \textit{Ibid.}

\textsuperscript{991} \textit{Ibid.}, p.65

\textsuperscript{992} http://www.observatorynano.eu/project/filesystem/files/Cosmetics%20report-April%202009.pdf

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benefits to the consumer, such as those discussed above. However, the application of nanomaterials in cosmetic products has been the subject of continuous debate in the past few years and will continue to be. One of the main issues concerning nanotechnology in cosmetics is that of toxicity. There has been a lack of agreement regarding safety generally and also on whether dermal use is safe.

7.3 Part II: Regulation on Nanotechnology Used in Cosmetics (Nano-Cosmetics)

Introduction
The regulation of products of nanotechnology is considered a dynamic and growing activity, due to the wide spectrum of nanomaterials, nano-enabled products, and applications that are being developed and the uncertainties and appropriate testing for safety and efficacy. Government agencies and other organisations worldwide are formulating means by which to categorise nanomaterials (or products containing nanomaterials), assess their safety, understand the potential risks associated with their manufacture and use, and ultimately ensure that appropriate measures are taken to protect humans and the environment from any potential harmful effects.

Part I has previously considered the benefits of using nanomaterials in cosmetics, such as TiO2 and ZnO, however, concerns have been raised about even the ones that are considered safe. In the EU for example, while the use of titanium dioxide has been allowed as a UV filter in all sizes at ‘a maximum concentration of 25...
percent, there have been concerns expressed by the SCCP about its safety when applied to damaged/burnt skin. Similar concerns have been voiced about zinc dioxide. One of the key problems here is how much safety that the cosmetic manufacturers actually conduct. For instance, some producers make claims that their products are 'photostable' i.e. do not produce free radicals when exposed to UV rays, or that they 'help to keep free radicals at bay.' However the safety evaluations behind these claims are difficult to investigate because producers disclose little information about them.

Reliance on the regulator to establish certain measures to regulate nano-cosmetic has also been subject of continuous debate. It must be remembered, however, as far as regulators are concerned, they have to contend with a number of issues when dealing with the potential risk of nanomaterials. These challenges relate to a series of uncertainties, such as future developments, the speed of these, the new commercial opportunities that will arise, the dangers that will need to be overcome and most importantly whether the current regulatory framework can cope. Lack of data on nanomaterials and the suitability of testing methods is a major obstacle to an effective implementation of regulations. The regulation of risk in such uncertain conditions is common in chemical and cosmetic safety. It is suggested that it is too early to analyse if the existing regulatory frameworks can and will be effective to cover the potential risks due to a considerable knowledge gaps on safety and the health and environment risks from certain nanomaterials. The next part examines the possible regulations that could regulate nanotechnology in cosmetics particularly in terms of their safety. The discussion will also continue as to whether the existing regulation is adequate to cover and control nanotechnology used in cosmetic products.

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998 Based on scientific opinion adopted on 24 October 2000 by SCCNFP (SCCNFP/0005/98). However, a review of substances in its nanoform deemed necessary according to SCCP/1147/07, ibid.
999 Zinc oxide, on the other hand, has only been assessed as safe for use in its bulk form, although several companies told us that they use it in nanoform. The SCCP started to consider the safety of nano zinc oxide in June 2003, but requested more information from manufacturers to enable a proper safety evaluation. In its most recent opinion published earlier this year, the SCCP called for a reevaluation of nano titanium dioxide and zinc oxide used in sunscreens, particularly in relation to damaged skin and to assess the effects of mechanical action from rubbing in the lotion or flexing the skin. It also called for the data that industry submits to demonstrate safety to be publicly available.
1001 See Small Ingredient Big Risk, supra note 80
7.4 Evaluating What Will Work in Regulating Nano-Cosmetics

It is submitted that regulation has a significant impact on the technology development. The lack of regulation, particularly in nanotechnology, can affect not only the safety of the consumers but also the environment and health. However, it is acknowledged that an overly strict regulation, for example based on incomplete information or excessive vigilance, may equally cause disadvantages by limiting any benefits or by slowing developments. At present, nanotechnologies affect many areas of law: such as occupational health and safety, environmental protection, consumer protection, medical law, privacy and civil liberties, intellectual property and patent law. However, the study of the legal repercussion of nanotechnologies is just started. This is evident by the fact that up to now, a specific legal framework for nanotechnologies has only existed in the EU (although not yet implemented) but not in other jurisdictions. Although in principle, nanotechnologies can be indirectly regulated by the existing laws for different purposes. However, there is a concern as to whether and how much such existing structures suit nanotechnology and indeed other new technologies. It should be remembered that the point of having legislation is to safeguard consumer health and the environment against any toxins found in nanoparticles.1002

Marchant, Sylvester and Abbott1003 explore the debate on the potential regulation of nanotechnology. Adopting their approach to nano-cosmetic products brings about four important questions. Are the risks from nano-cosmetic products adequately characterised and serious enough to justify government regulation? If and when regulation is appropriate, what regulatory entity should undertake the regulation? Should nano-cosmetic products be regulated under existing regulatory authorities or under a new specific statute? Lastly, what regulatory instruments or approaches are most relevant and appropriate for controlling safety and risks for nano-cosmetics (perhaps using the same product safety principles such as pre/post-market control, reporting requirements, labelling products, restrictions or bans)?

In terms of the first question, it should be remembered that the risks posed by these products are still unknown. However, toxicity of nano-cosmetic has been researched quite extensively. The existing body of toxicology literature clearly

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suggests that nanoparticles have a greater toxicity risk to humans than larger particles. Research has shown\textsuperscript{1004} that nanoparticles can penetrate the skin. For example, titanium dioxide nanoparticles appear to cause much more damage to DNA than bigger particles. It is held that ‘whereas 500nm titanium dioxide particles have only a small ability to cause DNA strand breakage, 20nm particles of the materials are capable of causing complete destruction of super-coiled DNA, even at low doses and in the absence of exposure to UV.’\textsuperscript{1005} There are also several categories of nanoparticles that have been proven to be toxic to human tissue and cell which have resulted in increased ‘oxidative stress, inflammatory cytokine production, DNA mutation and even cell death.’\textsuperscript{1006} Fullerenes, even though they have been shown to be toxic to fish\textsuperscript{1007} and other water life as well as harbour bacteria are currently found in some creams.\textsuperscript{1008} Tests have shown that even small doses of fullerenes are toxic to human livers.\textsuperscript{1009} These are just a few examples, there are many others which are still being researched. It would be extremely dangerous to let such risks reach consumers; therefore regulation is needed to regulate nano-cosmetics.

As to which regulatory form should undertake the regulation, earlier chapters of this thesis have discussed the benefits and drawbacks of public regulation and self-regulation. It has been concluded\textsuperscript{1010} that public regulation is the most ideal system for cosmetics, compared to self-regulation, which is normally voluntary and has been the subject of much criticism. In dealing with cosmetics that contain nanomaterials, similar conclusions can be arrived at. This is because, through mandatory regulation, the elements of safety can be better ensured, such as in the

\textsuperscript{1004} Li Mu, and Robert Sprando, supra, 2010, p. 1748
\textsuperscript{1006} Small Ingredients Big Risk, \textit{ibid.}
\textsuperscript{1007}Oberdorster E, 'Manufactured Nanomaterials (Fullerenes C60 Induce Oxidative Stress In The Brain Of Juvenile Largemouth Bass,' \textit{Environmental Health Perspectives}, 2004, 112, pp.1058-1062
\textsuperscript{1010}See part III of the comparative chapter
compliance to certain important safety elements (information regulation, pre-market and post market control obligation), and also safety testing. A voluntary approach under self-regulation would of course be beneficial due to the fact that it saves costs (especially as nanomaterials will involve an enormous budgetary spend). Also, as has been stated, ‘[b]ecause resources are limited ... federal agencies need not to merely coordinate their activities but also to move toward cooperative and collaborative efforts.’ However, it must be remembered that one important element in the voluntary regime is that participation is also voluntary. Marchant, Sylvester and Abbott, for example, have mentioned that the most responsible firms which are likely to implement the practice of effective risk management regardless, will sign-up for any voluntary programme, while the bad ones who present the problem are not likely to sign-up. If these create safety problems, it will reflect badly on the whole industry. Also, it must be noted that SMEs (which also form a substantial portion of the nano-industry) lack resources, experience and information in a voluntary programme.

In addressing the third question, that is; should nano-cosmetic products be regulated under existing regulatory authorities or under a new specific statute, it is important to note that currently, a key issue in the regulation of nanomaterials in many developed countries is that it is not addressed under its own specific regulation. Rather, nanomaterials are placed under existing regulations, nanomaterial cosmetics being one of them. For instance, in the USA, the Toxic Substances Control Act regulates whether a new nanomaterial is a new chemical. This decision is significant because chemicals already known are not obliged to submit to tests by the responsible authority and are not subject to the scrutiny of pre-manufacture notice requirements. If the chemical is on the list, it may be used without review. Also, there is a possibility that producers of nanomaterials might not

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1013Ibid.
1014TSCA was enacted in 1976 with three principal policy objectives. First, ‘adequate data should be developed’ on the effects of chemicals on health and the environment and the development of data ‘should be the responsibility’ of chemical manufacturers. Second, the law states that ‘adequate authority should exist to regulate’ chemicals. Third, this regulatory authority over chemicals ‘should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation’ while fulfilling the primary purpose ‘... to assure that such innovation and commerce ... do not present an unreasonable risk of injury to health or the environment’
1015That is the EFA
want to have a specific statute devoted to nanomaterials because they may be much more stringently regulated than under existing statutes.

Finally, as to regulatory instruments or approaches that are most relevant and appropriate for controlling safety and risks for nano-cosmetics, the use of the same product safety principles, such as: pre-market control and post-market control, reporting requirements, information regulation, restrictions or bans - will help to create a safer product. It must be remembered that evaluating the potential risks in early product development creates an opportunity to safely manage them, so that a safer path forward can be taken. It has been mentioned that in products like cosmetics which have become one of the most important areas for the application of nanotechnology at the present time, the health risk is quite obvious. These can be controlled using pre-market and post-market compliance, mandatory labelling, safety responsibility as well as controlling the ingredients.

7.4.1 Pre-marketing control for nano-cosmetics

In respect of all the issues raised above, it is essential to note that pre-marketing control and post-marketing control can both play significant parts in managing nano-cosmetics. Although it has been mentioned earlier in the regulation of cosmetics, both pre-market and post-market controls are relevant in controlling this new emerging technology in cosmetics. It has been mentioned that product regulation does not mean the development of risk free products. Rather it is about ensuring that products only pose acceptable risk and that products are made safer by reducing their risks. This is true in the case of the use of nano-cosmetics where there are still many uncertainties as to their safety. Gary and Douglas for example, have mentioned that there has been increasing public concern about nanotechnology and this carries the risk that failing to act will turn nanotechnology into ‘another Frankenfood controversy’ as was the case with genetically-modified food where technology became so stigmatised that the public would not accept proof of its

1016 The discussion earlier is on the regulation of cosmetic without discussing the nanotechnology in cosmetic
safety. In Australia, consumer advocacy groups have called for a moratorium on nanotechnologies (they even called nanotechnology a ‘new asbestos’) until they are confirmed as safe, as per the precautionary principle. They are not the only ones who have called for such a moratorium. Friends of the Earth also share the same belief. While such groups have demonstrated their extreme objection to nanotechnology, is it fair to consider a total ban on such technology because of the uncertainties it poses? Patrick has suggested that such a reaction over nanotechnology is an over-reaction.

7.4.2 Precautionary principle

The question of what risk is acceptable and what is not, is debatable. Another important question concerns how to manage such risk (since it is quite impossible to invoke zero risk principles in this new technology). It appears that a number of manufacturers are keen to ascribe ‘nano’ characteristics to their products, claiming they give better results to the consumers while others prefer not to refer to it on the label, although they do admit to their use in their formulations. The issue here is how would they know that their own products are safe?

The precautionary principle approach has been suggested for nanotechnology given its potential and promising benefits which also comes with uncertain risks. The precautionary principle sets down that technology that has the potential to cause lasting damage needs to be proved safe, if only to a minimum standard. Once this assurance has been received the technology can then be developed and made available. Generally, it is an instrument helping the decision

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1020 Several groups have called for moratoria on distribution of products containing nanoparticles. The group GeneEthics Network has called for a ban of nanoparticles in sunscreen. See K. Dearne, Call for Ban on Nanoparticles, The Australian, October 4, 2005
1021 Friend of the Earth believed there should be a moratorium on the further commercial release of cosmetics that contain nanomaterials, and urged for withdrawal of such products currently on the market, until adequate public, peer-reviewed safety studies have been completed, and adequate regulations have been put in place. See Small Ingredient Big Risks, p. 5
1022 Lin, Patrick, 'Nanotechnology Bound: Evaluating the Case for More Regulation,' Nanoethics, 2007, 1: pp.105-122
1023 Ibid, p. 108
1024 For example see L’Oreal, Sustainability FactSheet, June 2010, at http://www.sustainabledevelopment.loreal.com/pdf/topics/Cosmetology.pdf (last accessed 17 May 2011)
1025 A survey by Which? to 67 cosmetic companies
1026 See Salmi, Anna. Talvitie, Julia, Pakkanen, Marjukka, Lipasti, Tanja. And Isometsa, Henri: ‘The Precautionary Principle and Nanotechnology,’ 5 April 2010, Helsinki. See also Lin, Patrick, 2007, pp. 105-122. Note that precautionary principle has been discussed in the theoretical chapter
makers to control uncertainty in relation to the potential risk of harm caused to safety, health and environment and it is said to function as a ‘redistribution of the burden of scientific uncertainty.’

Being widely adopted in the EU (although not defined in the EU Treaty or any other EU instrument, the application of this principle has been made statutory in the law of the EU) this principle has now also been considered in the USA. In terms of nanotechnology, the precautionary principle determines that if an action might possibly lead to an unacceptable consequence, then such an action should be stopped until that risk is mitigated. For our purposes, the principle states that if introducing nanotechnology products into the marketplace now might possibly lead to an unacceptable consequence of serious harm to the consumer or the environment, then such action should be refrained from until that risk is mitigated - in this case, by implementing stronger laws and regulations. In order to make the principle work, the risk must not be based purely on a logical possibility but must be more reliable.

It must be remembered that cosmetics that contain nanotechnology might not reach the degree of safety that is required from other products, for example, drugs or pharmaceuticals, which are treated in a much stricter way than other products by virtue of the strong grounds for believing that they may pose an inherent and unacceptable risk. Furthermore, the level of risk could depend on a number of factors, which include the type and vulnerability of the user and the extent to which the producer has taken precaution to guard against hazards and warn the user. A risk could also be the outcome of a manufacturing or production error or design/material used.

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1028 E.M, Gary and J.S Douglas, supra, 2006, note 24. Note that this principle is not defined in the EU Treaty or any other EU instrument, although the application of this principle has been made statutory in the law of the EU.
1029 The EU Communication 2000 states, ‘[A]lthough the precautionary principle is not explicitly mentioned in the Treaty expect in the environment field, its scope is far wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable ground for concerns that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with chosen level of protection.’ The Commission on the Precautionary principle, Commission of the European Communities, Brussels, 02.02.2000 COM, 2000.
1030 Lin, Patrick, op.cit., p. 116.
7.4.3  Mandatory labelling of nano-cosmetics (information regulation)

As far as the consumers are concerned, they are not able to anticipate risks and safeguard themselves against any danger caused by such products. Many nano-products are already available on the market, including nano-cosmetic. Unfortunately, it is very difficult for consumers to know which these are.\(^{1031}\) This is not helped by some companies who use nanomaterials but do not admit to it. Due to this, the Consumer Association of the EU (BEUC) demanded\(^ {1032}\) that nanomaterial labelling be made mandatory prior to the marketing of such products on the market including nano-cosmetics. However, it is noted that although labelling of consumer products with nanomaterials components could help consumer choose product, it is surrounded by complexities.\(^{1033}\) So far, neither the USA nor the EU have introduced legally binding consumer labelling requirements that specifically target nanomaterials. Although both jurisdictions are considering this in the form of technology-specific labels, the EU is much further ahead than the USA in this regard. In their new Cosmetics Regulation,\(^ {1034}\) (although it will only be applicable after 11 July 2013),\(^ {1035}\) there is a requirement that ‘[a]ll ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word “nano” in brackets.’\(^ {1036}\)

However, some have argued\(^ {1037}\) that the intention of these labels is not as a safety warning but purely for information purposes. Nevertheless it is still very important to give the consumer an informed choice. For example in a survey conducted by Holst and Strandbakken,\(^ {1038}\) they quoted a participant saying that ‘[w]e are the ones who have to say no, we are the ones who have to choose, so obviously we need information!’\(^ {1039}\) In addition, frequently consumers make decisions based on

\(^{1031}\) Throne-Holst, Pal Strandbakken, 'Nobody Told Me I was a Nano-Consumer: How Nanotechnologies Might Challenge the Notion of Consumer Rights,' *Journal of Consumer Policy*, 2009, 32(4), pp. 303-402

\(^{1032}\) BEUC or the Consumer Association of the EU as well as the UK Royal Society, are among the organization that urged for such labelling

\(^{1033}\) Holst and Strandbakken, p. 205. They identified 3 complexities in labelling nanoproducts; first, complexity about the size range, second, complexity due to fear of some information overloaded and third, complexity regarding level of knowledge about nanotechnology with general public. *Op.cit.*

\(^{1034}\) EC 1223/2009. Discussed in the EU chapter (chapter 3 part III)

\(^{1035}\) See the EU website http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm

\(^{1036}\) Article 19(1) of the new Cosmetic Regulation which will replace EU Cosmetic Directive EEC/76/798

\(^{1037}\) BEUC, 2006


\(^{1039}\) *Ibid.,* p. 304

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misconceptions about risks from products containing nanomaterials. It is perhaps relevant to relate the predicaments on nano labelling with the controversy over labelling of genetically modified food (GMF) a few years ago.

Some have asserted that it is good for consumers on the basis that consumer should know what they consume.\textsuperscript{1040} Labelling obligations on GMFs will allow consumers to be made aware of the existence of the GMF and therefore give them the choice to either buy or not. On the other hand, there are others who strongly believe that the labelling will imply that there is something wrong with the product, which consequently may lead to trade barriers.\textsuperscript{1041} It should also be remembered that there are consumers who will simply not know how to interpret whether GMF/nano is good or bad. For example it has been suggested by Heidenstrøm \textit{et al.}\textsuperscript{1042} that variety of labels ‘may appear like a jungle for consumers,’ such as a chaos of symbols, images, logo and text. However, since primary consideration should be given to consumer safety, as the risk coming from nano-cosmetics is still far from certain, it is necessary for the public to be protected against unreasonable, unnecessary and preventable risk of injury from the foreseeable use of such products. In this case, such a situation justifies the intervention by regulators to make the labelling of nanomaterials mandatory.

7.4.4 Post-marketing control for nano-cosmetics (batch marking, withdrawal, recall, seizure)

Post-marketing control is concerned with product monitoring in the marketplace. If cosmetics that contain nanomaterials are found to be hazardous\textsuperscript{1043} and are already in the marketplace, it may not be sufficient to only prohibit their use - they may need to be removed and disposed of. Product recall is important as is a tool for monitoring cosmetic products,\textsuperscript{1044} similar monitoring is also suitable for nano-cosmetics. It is also thought to be feasible for nano-cosmetics as batch numbers are attached so that they can be traced. It is however, important to note that this power should only be

\textsuperscript{1040}Salmon, Naomi, ‘A European Perspective on the Precautionary principle, Food Safety and the Free Trade Imperative of the WTO,’ \textit{European Law Review}, 2002, Sweet and Maxwell

\textsuperscript{1041}Ibid.

\textsuperscript{1042}Heidenstrøm, Jacobsen, Borgen, ‘To Select or to Ignore: Consumer Strategies for Manoeuvring the Label Diversity,’ \textit{Oppdagsrapport 2}, 2011, SIFO, Oslo.

\textsuperscript{1043}There is yet a report on the adverse effects of cosmetics that contain nanomaterials

used as a last resort, when no other measure is left to the authority. Once the notice has been served, the responsible person needs to carry out the product recall as per the requirements in the notice. If withdrawal and recall are successful, seizure of such products is thought to be necessary. This is due to the fact that unscrupulous traders may try to dispose of them to gullible consumers or they could even pass into the hands of traders who do not appreciate the danger.

In conclusion, in evaluating what regulations are most suitable for nano-cosmetics, it is thought that comprehensive regulations on nanotechnology would be the ideal. Given so much concern over safety, evaluating the potential risks in early product development creates an opportunity to safely manage them, so that a safer path forward is ensured. It has been mentioned that in products like cosmetics which have become one of the most important areas for the application of nanotechnology at the present time, the health risk is quite obvious. As such, particular attention is required for the long-term safety aspects of nano-cosmetics, due to the fact that such products may be used extensively by a person over a long period of time. The effect of its efficacy or defects might only emerge after a considerable amount of usage. Consequently, post-marketing obligations for cosmetic products are also important as they will enable the producer to be informed of the risks that appear from the use of such cosmetics, as well as enabling appropriate action to be taken when there is any possibility of danger resulting from such use in the long term of these materials in cosmetic products.

7.5 Part III: Regulation of Nano-Cosmetics: A Comparative Approach in the USA, the EU and Malaysia

Introduction

This part examines the current approach that has been/ is being taken in the three mentioned jurisdictions for cosmetic products that contain nanomaterials. The EU and the USA are the two frontrunners in the field of nanotechnology and therefore the regulations that they put in place in response to the risks will be scrutinised and followed throughout the world. It is submitted that Malaysia, as a developing country, is still on the way to preparing itself to accommodate the global development of nanotechnology. Although there are serious efforts for the

\[1045\textit{Ibid, p. 2}\]
development of nanotechnology in Malaysia, the development of nanotechnology in cosmetics is still at a slower pace. This part deals with the current regulations on how nanotechnology in cosmetic is regulated in the EU and USA, and Malaysia, as well as some issues as to the inadequacy of such regulation in those jurisdictions.

As mentioned in the comparative chapter, cosmetic regulations in the USA, the EU and Malaysia have similar aims although different tools are applied. There are however certain differences with regards to significant implications for how nanocosmetics may be regulated in each jurisdiction. The introduction of the new Cosmetics Regulation seems to have a significant impact on cosmetic products, including cosmetics that contain nanotechnology. In the existing safety framework for cosmetics, it is submitted that none of the compared jurisdictions in this thesis explicitly refer to nanomaterials, either in statutory language or in regulations. The newly introduced EU Cosmetics Regulation, which is replacing the existing Directive, however, has particular reference to nanomaterials used in cosmetic products. This means that the Regulation is the first mandatory legal document to define ‘nanomaterial.’ The Regulation specifies binding requirements for products that meet the definition of nanomaterial, particularly concerning the information submitted as well as in labelling. The specific nanoproduct provisions are very different to the existing practice in the USA, where nanomaterials are regulated under existing regulation, as are all other emerging technologies. The next section examines the regulatory schemes for nanotechnology in the USA, the EU and Malaysia.

7.5.1 Cosmetics and nanotechnologies in the USA

It was suggested that the debate about the regulation of nanotechnology in the USA closely track the earlier debates about regulation of biotechnology. This is due to the fact that both involved considerable uncertainties and little consensus about

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1046 For example in the Third Industrial Master plan (IMP) that spans between the years of 2005-2020 (15-years). By the end of 8th Malaysian Plan, Malaysia has spent more than RM160 million on various areas of nanotechnology related project. See Halimaton, Hamdan, ‘Nanotechnology in Malaysia: A New Paradigm,’ a keynote paper in National Seminar of Nanotechnology, 2008

1047 Note that Malaysia, being a member of ASEAN countries has decided to adopt the ASEAN Cosmetic Directive in 2003 which has the essence of the EU Cosmetic Directive EEC/76/798 thereby following all the EU pathways on the regulation of cosmetic. See chapter 5 – the Malaysia chapter and chapter one (introduction chapter) on how the harmonization of cosmetic regulation has taken place in ASEAN in 2003

1048 It is scheduled to be implemented on 11 July 2013.

1049 G. Marchant, D. Sylvester and K.W. Abbott, op.cit., p. 190
what authority the technology should be regulated. In the USA, the FDA is one of the most proactive agencies in addressing nanotechnology. Regarding the regulation of this new emerging technology, Risk Policy Report\textsuperscript{1050} stated that no new statutes are required to regulate nanotechnology. Card and Magnuson\textsuperscript{1051} have stated that the point where the FDA regulates nano-products does not depend on the component materials or method of manufacture but is based on the actual product. They contend that some nanotechnology-based products are likely to span regulatory boundaries between drugs, medical devices and biological products; although there are established pathways to regulate such combination products. In this regard, the principal form of action of the nanotechnology-derived product will determine the regulatory framework.\textsuperscript{1052}

The Nanotechnology Task Force was established by the FDA in 2006; it was given the task of determining the regulatory framework that promotes the development of safe, effective and innovative FDA-regulated products that use nanomaterials.\textsuperscript{1053} A 2007 report\textsuperscript{1054} by this Task Force stating that the FDA’s authority over products that require pre-market approval, such as drugs, biological products and food, was comprehensive, and that it authorised the FDA to get the scientific data that is needed to evaluate the safety and effectiveness of products, including the relevant effects of nanoscale materials.\textsuperscript{1055} However, in terms of those that do not require pre-market approval such as cosmetics, food and dietary supplements ‘generally recognized as safe’ (GRAS), the FDA is encouraged to help the producers to pinpoint information to evaluate the safety of products that have nanoscale materials. This includes data on long-term and chronic toxicity.

It has been noted by the Nanotechnology Task Force that nanomaterials, like other emerging technologies are difficult to regulate. These difficulties are magnified because nanotechnology can be used in any product regulated by the FDA and because ‘at this scale, properties of a material relevant to the safety and (as

\textsuperscript{1051}\textit{J.W. Card and B. Magnuson, ‘Regulation of Nanomaterials Today and Tomorrow,’ InsideCosmeceutical.com, April 1, 2011.p.1}
\textsuperscript{1052}\textit{Ibid.}
\textsuperscript{1053}\textit{Nanotech Task Force, ‘Public Meeting on Nanotechnology Materials in FDA Regulated Products,’ October 2006.}
\textsuperscript{1054}\textit{Department of Health and Human Services of the FDA, \textit{Nanotechnology Task Force Report}, July 25 2007}
\textsuperscript{1055}\textit{Ibid.}
applicable) effectiveness of FDA-regulated products might change repeatedly as size enters into or varies within the nanoscale range.\textsuperscript{1056} The U.S. Consumer Product Safety Commission (CPSC) has stated that as with other compounds found in consumer products, the safety of nanomaterials can be evaluated under existing CPSC regulations and guidelines.\textsuperscript{1057}

It was mentioned that since CPSA mandated neither approval nor registration for products covered under its jurisdiction, the CPSC therefore does not assess a product’s potential risk to the consumer until after it has been placed on the market. Producers of nanomaterials are under the same reporting obligations as producers of other products with regard to safety effects. This requires them to report information to the CPSC that suggests a product is in breach of a regulation, is defective and as such hazardous.\textsuperscript{1058}

The FDA has, up until now, treated nanotechnologies in cosmetics in line with the Task Force Report mentioned above. While for other categories of product; the FDA has agreed that nanomaterials may pose potential risks, but regards such risks to be uncertain. Therefore, it is unlikely that nanomaterials are regulated in their own category. The Nanotechnology Task Force Report acknowledged that it only receives reports regarding the cosmetics’ adverse effect when they are voluntarily supplied.\textsuperscript{1059} The FDA admitted that there was a chance that some products used nanotechnology without them being informed, that it only had limited authority and that new tools may be needed to manage this new technology.

Acknowledging these problems, the FDA has considered the Task Force’s proposal for cosmetics, such as assessing methods for testing to determine safety and quality of product as well as requiring companies to submit data on the effects of nanomaterials on product safety. As well as providing regulatory support for cosmetics,\textsuperscript{1060} the FDA has responded to a one-off request for regulatory support regarding sun creams. These are considered to be drugs in the USA but cosmetics in the EU. The FDA received a petition in 2006 from the International Center for

\textsuperscript{1056}FDA 2007
\textsuperscript{1058}Ibid.
\textsuperscript{1059}FDA, 2007a, p. 15
\textsuperscript{1060}See details in the USA chapter
Technology Assessment (ICTA) and other NGOs\textsuperscript{1061} asking it to change the regulations regarding nano-engineered particles in products, particularly suncreams.\textsuperscript{1062} However, in August 2007 the FDA proposed a rule to change the OTC monograph for sunscreen, and requested comments on the safety and effectiveness of nanoscale particles in suncreams.\textsuperscript{1063} In April 2012,\textsuperscript{1064} the FDA has published draft guidance for the cosmetics industry containing recommendations on producing nano-cosmetics. However it continues to maintain its current position on regulating nano-cosmetics despite agreeing that the safety evaluation that has been used for traditional cosmetics may not be completely suitable to nano-cosmetics.\textsuperscript{1065}

\subsection*{7.5.2 Cosmetics and nanotechnologies in the EU}

In the EU, it has been explained that the current EU Cosmetics Directive does not include any particular reference to nanomaterials. Despite that, the EU Commission, however, claims that nanomaterials’ health related risks are actually broadly covered, as the Commission highlighted that because they were obliged to carry out risk assessments and they were able to set, through legislation, strict conditions of use for particular ingredients, these risks can be dealt with in an appropriate manner.\textsuperscript{1066} The Commission however admitted that a revision of the current framework may be necessary.

The Commission sought to establish several requirements in its proposal for the Cosmetics Regulation: minimum requirements for cosmetic safety assessments, greater cooperation between member states, a coordinated risk assessment system, an obligation on industry to report serious undesirable effects, and a centralised notification requirement. In the initial draft, nanomaterials were not mentioned however amendments subsequently rectified this and these were approved by the

\begin{thebibliography}{99}

\bibitem{1061} Friends of the Earth, Greenpeace, Action Group on Erosion, Technology and Concentrations, Clean Production Action, Center for Environmental Health, Our Bodies Ourselves, Silicon Valley Toxics Coalition.


\bibitem{1063} FDA, 2007e

\bibitem{1064} CFSAN (FDA), ‘Guidance for Industry on Safety of Nanomaterials in Cosmetic Products,’ April 2012.

\bibitem{1065} \textit{Ibid.}, pp. 6-8

\bibitem{1066} European Commission, 2008 g, 17.

\end{thebibliography}
European Parliament in its first reading in March 2009.\textsuperscript{1067} It can be seen that there are significant changes concerning the regulation of nanomaterials in cosmetic products which also attempt to make regulatory oversight of cosmetics more robust and unified in the EU. Also, it also aims to establish legal certainty by putting them explicitly in the text.\textsuperscript{1068} As mentioned earlier, not only does the regulation define such materials it also requires them to be labelled properly on cosmetic products.

The Regulation defines a nanomaterial as `[a]n insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.'\textsuperscript{1069} As regards to the continuous and diverging uncertainty concerning the definition of nanoscale substance, Article 2 (Para 3) affirms that, '[i]n view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (k) of paragraph 1 [quote above] to technical and scientific progress and with definitions subsequently agreed at international level.'\textsuperscript{1070}

As well as the definition, the new Regulation has specific guidelines on safety assessments and the safety report for cosmetics, which is compulsory for all producers. The assessment must include information on the expected systemic exposure to specific ingredients in a finished formulation. The safety report must also be kept updated even if further information comes to light after the cosmetic product is placed on the market.\textsuperscript{1071} In addition, when assessing exposure to a cosmetic product, the manufacturer must give particular consideration to `[a]ny possible impacts on exposure due to particle size' and, with regard to the toxicological profile of a product, particular consideration must be given to particle sizes and nanomaterials, as well as to the interaction of substances.\textsuperscript{1072}

\textsuperscript{1068}The current version of March 2008 contains 28 such references, European Commission, 2008h.
\textsuperscript{1069}Article 2 Paragraph 1(k).
\textsuperscript{1070}European Parliament, 2009b. Moreover, a Commission statement accompanying the recast regulation explicitly states that, '[o]n definition of nanomaterials the Commission notes that work towards a common definition of nanomaterials is still evolving. The Commission therefore confirms that in future Community legislation progress on the common definition should be taken into account and notes that the cosmetology procedures contained within this proposal also allow for the updating of the definition within this proposal.'
\textsuperscript{1071}Article 10, Paragraph 1(a) and (c)
\textsuperscript{1072}Annex I, Paragraphs 6 and 8
The ‘responsible person’ must keep a product file that a relevant competent authority can consult easily. This must describe the method of manufacture and include the product safety report. The regulation also states that before putting a product on the market, the responsible person must inform the Commission of any nanomaterials contained in it along with a means of identifying them including the chemical name (IUPAC) and other descriptors as stated in paragraph 2 in the Preamble to Annexes II to VI. He must also tell the Commission about the ‘reasonably foreseeable exposure conditions’. This information will be passed on to relevant national authorities for the purposes of market supervision. In fact, a final report on NanoSafety by the EU Commission highlighted that the EU Cosmetics Regulation was the first EU regulation to solely devote a whole article (Art. 16) to nanomaterials.

In Article 16 (para. 1), it specifies that for every product that contains nanomaterials, ‘[a] high level of protection of human health shall be ensured’. Moreover, cosmetic products containing nanomaterials have to be reported to the Commission six months before being placed on the market, with the following information to be provided:

a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in paragraph 2 of the Preamble to Annexes II to VI;
b) the specification of the nanomaterial including size of particles, physical and chemical properties;
c) an estimate of the quantity intended to be placed on the market per year;
d) the toxicological profile of the nanomaterial;
e) its safety data related to the category of cosmetic product as used in it;

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1073The term ‘responsible person’ as defined in Article 4 generally refers to the importer or manufacturer of a cosmetic product, see European Commission 2008h.
1075The timeframe for notification of cosmetic products containing nanomaterials that are currently on the market has not yet been fully determined in the present version of the Regulation. Moreover, an exemption from these requirements exists for cosmetic products containing nanomaterials in conformity with requirements set out in Annex III (restricted substances) and for those products where nanomaterials are used as colorants, UV filters or preservatives, which are subject to specific safety testing requirements as outlined in Article 14 and the respective annexes. European Commission, 2008h
1076The regulation explicitly allows the Commission to add requirements due to technical and scientific progress. See European Commission, 2008h, art. 16.
f) the reasonably foreseeable exposure conditions. (Article 16, Paragraph 3(a)-(f)).

In addition, Article 19 of the Regulation specifies a general labelling for nanomaterials that 'All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets.'

The legal foundation on which the regulatory system is based is in the process of being rewritten. This makes it a little difficult to assess the efficiency of current cosmetics regulation and the place of nanomaterials in it. There has not been a great deal of experience of the way the Cosmetics Directive can be applied to nanomaterials, and as for the Cosmetics Regulation, it has not been finalised so the situation is equally unclear. Due to the uncertainty, and in line with common practice, the EU has chosen a case-by-case approach to risk assessments of nanomaterials. The SCCP has already assessed a few nano ingredients, mainly those used in suncreams, such as, titanium dioxide (TiO2) in 2000 and zinc oxide (ZnO) in 2003. Although the SCCP allows titanium dioxide for use in sunscreen products, the SCCP however, highlighted that more data was required to approve a suitable safety assessment of nanoscale zinc oxide for use as a UV filter.

The SCCP published its opinions on nanomaterial safety in cosmetics, in 2007. It stressed the paucity of solid knowledge and the difficulties in assessing their risk. An example it gave related to insoluble nanoparticles whose toxicities cannot be adequately assessed under standard mass metric methodologies. It also pointed out 'large data gaps in the risk assessment methodologies and in regard to data on the nanoparticles in cosmetic products via inhalation and ingestion'.

In terms of new scientific data, the SCCP deemed it necessary to reassess the safety of nanoparticles of titanium dioxide. The new Regulation is on course to keep the ‘case-by-case’ basis of the risk assessments it carries out, but is also likely to

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1077Discussed in earlier section
1078The initial decision referred to a lack of reliable data on absorption by the skin. See SCCP, Statement on Zinc Oxide Used in Sunscreens, at http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_00m.pdf (accessed 8 July 2009)). These data have apparently been made available and the SCCP is currently re-evaluating its decision. See European Parliament, ‘Parliamentary Questions & Answer,’ by Mr Verheugen on behalf of the Commission at http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2006-2811&language=EN (accessed 8 July 2010).
1079Eco-toxicity means the adverse effect of a chemical, biological or physical on an ecosystem
1080SCCP, 2007, pp. 5-6.
1081Ibid., p.6.
provide a more robust legal framework for consolidating a system of market surveillance and consumer labelling. This reasserts the position of cosmetics regulation as a highly developed regulatory approach for nanomaterials in consumer products. However, the Cosmetics Directive will remain in force until the Cosmetics Regulation is fully implemented in 2013.

7.5.3 Nanotechnology in Malaysia’s cosmetic regulation

Nanotechnology in Malaysia is mandated by the Ministry of Science, Technology and Innovation (MOSTI). The Intensification of Priority Research Areas (IPRA), a programme of the Eighth Malaysia Plan (8MP)\textsuperscript{1082} marked nanotechnology as a priority research area (one of 14 identified),\textsuperscript{1083} and it categorised it under ‘Strategic Research’ (SR).\textsuperscript{1084} At the end of the Eighth Malaysia Plan,\textsuperscript{1085} MOSTI awarded about RM160 million (equivalent £32 million) towards research projects related to nanotechnology. Nanotechnology was included as a priority area under IPRA for the 8th & 9th\textsuperscript{1086} Malaysia Plans with the intention of building a nanoscience specialism in the country, to include state-of-the-art nanotechnology laboratories as well.\textsuperscript{1087}

In order to achieve this Malaysia has begun by identifying potential researchers in nanotechnology, upgrading laboratory facilities, and preparing a development programme for producing future scientists specialising in nanotechnology.\textsuperscript{1088} MOSTI is now in charge of leading the planning and development of the National Nanotechnology Initiative (NNI). Cosmetics that contain

\textsuperscript{1082}Since Malaysian independence from the British on the 31\textsuperscript{st} August 1957, the Economic Unit of Malaysia has prepared 9 Malaysian Plans. (1\textsuperscript{st}– 9\textsuperscript{th} Malaysian Plans). Each and every Plan has its own objective, but the primary objective of all the Plans is to improve the Malaysia’s economic status and to provide Malaysia at par with other competitive nations, as the former Prime Ministry of Malaysia has stated, ‘[T]he strategies and programmes presented are aimed at putting the nation on a stronger footing and to more resilient and competitive,’ Dr. Mahathir Mohamad (the Prime Minister at the time) in his speech during the introduction of the 8\textsuperscript{th} Plan.

\textsuperscript{1083}See \url{http://www.epu.gov.my/eightmalaysiaplan} (last accessed 12 May 2011)

\textsuperscript{1084}The SR projects are for a maximum period of 60 months, with potential for enhancing future competitive socio-economic development or new breakthroughs with commercial potential. Additionally, the projects must be multi-disciplinary, and have industrial linkages, with potential for commercialization.

\textsuperscript{1085}The 8\textsuperscript{th} Malaysia Plan is from 2001-2005

\textsuperscript{1086}The 9\textsuperscript{th} Malaysia Plan is from 2006-2010

\textsuperscript{1087}Halimaton Hamdan, ‘Nanotechnology in Malaysia: A New Paradigm,’ 2007, p. 63

nanotechnology are now being researched under SIRIM Berhad, through its Industrial Biotechnology Research Centre (IBRC). At the moment, the jurisdiction of this Centre is only to conduct testing concerning cosmetic products that claim to contain nanomaterials in their formulations. It has been insinuated by the General Manager of the Centre that there are many companies that claim to contain nanomaterials, however, many such claims have not been substantiated. For example, according to the Malaysian ISO Standard, the nanoparticle size that can be claimed to be ‘nanotechnology in cosmetics’ is between 1-100 nanoparticles. However, in practice, as long as the size is below 200 nanoparticles, the manufacturers can (just) claim that their products are nano-cosmetics. It has also been highlighted that there are some instruments and infrastructures that are still inadequate. It has also been highlighted that the infrastructure is inadequate. For example, there is only one available zetasizer (an instrument that measures the size nanoparticles) and more are needed.

7.6 Comparative analysis of the regulation concerning nano-cosmetics (the EU and the USA)

It must be noted that in this analysis, much of the comparisons are mainly between the USA and the EU. This is due to the fact that Malaysia has followed the EU path in terms of cosmetics regulation. Therefore, most of the comparisons will only be between the USA and the EU because of this. The comparison is done by specifying certain product safety important elements in nano-cosmetic context.

7.6.1 Incorporation of nano-specific regulatory language

A good measure for assessing the interest in nanomaterials in the USA and the EU can be found in the references to it in legislation. In the current practise, neither the FD&C Act nor the Cosmetics Directive make explicit mention of nanomaterials, in statutory language. However, the EU Cosmetics Regulation, has a specific reference to nanomaterials used in cosmetics. It is the first mandatory legal authority to define

1089 SIRIM Berhad is wholly owned by the Malaysian Government under the Ministry of Finance Incorporated
1090 A discussion with the General Manager of the Industrial Biotechnology Research Centre, SIRIM Berhad, Shah Alam, Selangor, Malaysia dated 17 April 2011
1091 Ibid.
1092 By virtue of the harmonization of cosmetic regulation in ASEAN- see previous discussion and in Chapter 5
the term nanomaterial, and at the same time admitting that the definition will evolve with developments in this field. It also includes specific provisions that apply only to nanomaterials, including information required and labelling. A contrast can be made with the USA, in that it seeks to regulate nanomaterials under existing regulation as it has done for other new technologies.

7.6.2 Pre-market tools
In terms of nanomaterials, unless size of particle is specifically included as an element in the regulations, nanoform and bulk substances are treated the same as ‘traditional’ cosmetics. The FD&C Act, however, does not prevent the FDA from limiting nanoscale ingredients separately from their bulk counterparts. If the FDA determines that a particular nanomaterial makes a product harmful to consumers under normal conditions of use while the bulk form does not, then they can decide to declare that the nanoform ingredient is an adulterant. This approach is similarly taken by the EU in the current regulation (before the implementation of the new Cosmetics Regulation which is scheduled in 2013) that is; all cosmetics are being regulated in the same way – regardless of whether they have nanomaterials. This means that particle size would be taken into account in the safety assessments to ensure that the product was safe. The existing Directive does not require any product notification provisions. However, once the Regulation is implemented, pre-market obligations for nano-cosmetics will be expanded to include product notification, but not product authorisation. Although no distinctive product safety assessment is necessary for nanomaterials, the Regulation introduces notification requirements that require the disclosure of any substances that are in the form of nanomaterials, their chemical identification, and their reasonably foreseeable exposure conditions.

Another requirement that can also be regarded as the pre-market tools for cosmetic containing nanomaterial is the notification obligation, to be filed by the producers six months before placing such products on the market. The time can be used by the Commission to request a safety assessment from the SCCP, and it must give its response within this timeframe. The SCCP’s opinion forms the basis for the Commission to ask for further information so that it can determine whether the nanomaterials are safe for their intended use and also to decide whether to allow,

\[1093\] European Commission, 2008h, art. 2 §§ (1)(k); 2(3).
\[1094\] Also in Article 16 as mentioned on the previous discussion
restrict, or prohibit their use. The Regulation also specifically enables listing in the Annexes based on lack of information.

It has been argued\(^{1095}\) that both the EU and the USA regimes have the ability to restrict the use of specific nanomaterials in cosmetics, although the requirements for deciding this differ and are likely to diverge further once the Regulation is implemented. Apart from this similarity, the EU regime demands additional notice and safety assessments. Disclosure of the presence of nanomaterials do not form part of these additional requirements, however this situation is set to change with the implementation of the Regulation.\(^{1096}\)

### 7.6.3 Labelling

It is significant that the FDA has stated that nanoscale ingredients contained in products will not need to be listed on the label. This is because it does not believe this information would be of any practical use to consumers, given that their risks are unclear.\(^{1097}\) In the EU, both the Directive and the Regulation require specific information to appear on the label, but whereas the Directive does not need nanomaterials to be mentioned the Regulation does – stating that these should be clearly included under the list of ingredients.\(^{1098}\) It includes a positive requirement for disclosure of nanomaterials, which marks a significant change in the requirements for labelling.\(^{1099}\) This practice is thought will be very useful to the consumers.

### 7.6.4 Post-marketing obligations for nano-cosmetics

As explained in the previous chapters, both the USA and the EU exercise post-marketing surveillance in their cosmetics systems, however, the activities implemented are different. A number of activities are carried out in these systems – cosmetics recalls, record inspection, GMPs and adverse event reporting.

Product recalls


\(^{1096}\) Ibid.

\(^{1097}\) Ibid., p. 89

\(^{1098}\) European Commission, 2008h, art. 19(1).

\(^{1099}\) Ibid.
The FDA can only request to recall cosmetics products in certain circumstances, as it requires the FD&C Act to sanction a recall or to remove products that are adulterated or misbranded with a court order. By contrast, the EU, via the Cosmetics Directive, lets states remove or stop products from being on the market, even if that product complies with the Directive, if it is considered that the product is a danger to human health. The Directive makes no explicit statements about the actions that can be taken if the Directive or national authorities are not heeded by producers. In contrast, the Cosmetics Regulation does comment on non-compliance, and it gives the Commission authority to take appropriate measures – either through recall or withdrawal of the product. If products comply with the Regulation but nevertheless present a danger to consumer health, the Regulation further allows for withdrawal, provisional recall or prohibitions.

Reporting of adverse effects
The FDA has stated that a barrier to the regulation and compilation of nanoproduct information is that it is not able to insist on the reporting of adverse effects for some types of products - including cosmetics. The Cosmetics Directive also lacks similar requirements for adverse event reporting. However, it can require producers to compile, within the PIF, data they already have on any undesirable effects. The Regulation is different in that it specifically requires producers and distributors to notify the relevant authority when a serious undesirable effect occurs.

7.6.5 Information sharing
Regulators in the USA and the EU have recognised certain predicaments in determining the adequacy of data, in terms of the assessment of the safety of nanomaterials on the market as well as the presence of products containing nanomaterials, particularly for cosmetics. Attempts to obtain this information for cosmetics may be restricted by the relevant legislation and by the agency’s ability to disclose confidential information. They acquire this information through both compulsory disclosure and voluntary submission. The EU Cosmetics Directive and the ASEAN Cosmetic Directive, requires pre-market authorisation for UV filters,

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1100 Compared to the CPSC jurisdictions under the CPSA, mentioned in the USA and the comparative chapters
1101 Article 12
colourants and preservatives, and the Regulation would need to receive notification before a nanoproduct was marketed. As discussed previously current notification and inspection authorities give additional sources of information, although they may not possess actual data on nanomaterial ingredient safety. The FDA does not have the authority to seek similar disclosures for cosmetics containing nanomaterials, although colour additives and drugs, including suncreams, require pre-market approval. The USA instead created the VCRP to encourage submission of data on a voluntary basis on products already on the market. Data on cosmetics ingredients that have been submitted to the VCRP are subject to disclosure under the Freedom of Information Act. However, a request for them to remain confidential can be made by a producer. The FDA has in place regulations that govern how it will respond to these and enables submissions to be retracted that are not going to be considered confidential.1102

The FDA can also obtain data from the CIR. This information is not automatically available to the public because it is a non-governmental entity. Having said this, the CIR publishes its studies in journals and it does disclose a certain amount of information to the public through its own procedures.1103 Information that is disclosed under these procedures includes data on safety and information that has been submitted to it. Information that is not disclosed includes: records relating to any substance exempt from disclosure as determined by the FDA – normally those that are confidential or a trade secret; and reports of adverse effects, unless FDA regulations state otherwise.1104 Parts of the meetings of CIR expert panels where non-disclosable information is considered should not be publicly available (this includes the FDA liaison).1105 As previously discussed, agencies might wish to share information, but might be unable to do so because of restrictions placed on them by statute, such as Section 331(j) of the FD&C Act which prohibits the disclosure of trade secrets. The FOIA and Regulation 1049/2001 regulate information disclosure in the USA and EU respectively. Both of these statutes make exceptions to disclosure, but allow them to share even confidential or trade secret information, as long as its privacy is protected. The FDA and DG Enterprise and Industry have agreements in

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1102 21 C.F.R. § 720.8.
1103 CIR, 2009, § 51.
1104 R. Faulkner, L. Breggin, N. Jaspers, J. Perdergrass and R. Porter, op.cit, p.90
1105 Ibid.
place which allows them to share information on cosmetics.\textsuperscript{1106} The FDA has similar agreements with other member states, because of this, they can share information and it will remain unavailable to the public. Having said that, information on nanomaterials is not currently included in these agreements, and this will remain the case until the Regulation is implemented.

7.7 Conclusion: Are we ready?
Nanotechnology is currently in a stage of infancy. While many products incorporating nanotechnology are already available, there are still significant knowledge gaps particularly with regards to the understanding of the potential risks presented by this technology. Nano-cosmetics are one of the leading nano-related sectors compared to other nanoproducts. In so far as regulation is concerned, the approaches to regulating nano-cosmetic in particular are divided into two; first; to treat nano-technology like any other product and regulate them under the existing statutes no different from non-nano products. In the case of nano-cosmetics, this approach means that they should be treated like other traditional cosmetics. This is what is currently practised in the USA, although they acknowledge that there is still a lot more research to be done on this technology. The EU approach is different, as they seek to regulate nano-cosmetics using specific provisions in the new EU Cosmetics Regulation. With such provisions, the EU is moving forwards to introducing new legislation that will specifically govern nano-cosmetics, which is a first anywhere in the world. That means the two jurisdictions are very far from each other. For Malaysia, it is still too early to gauge what will happen as far as nanotechnology is concerned, and particularly nano-cosmetics, as the ASEAN regulatory authority is still discussing this matter.

It is not yet possible to determine which of the regulatory schemes is the most efficient for regulating nano-cosmetics, as evaluations cannot be made until the regulatory implementation has been put in place. Is it the USA’s approach of ‘maintaining the status quo’ or the more proactive EU scheme which includes specific nano-cosmetic provisions? It may appear that the USA system is the least proactive, because it recognises that nanotechnology is still evolving, yet sees no issue with regulating it under existing legislative arrangements. Not taking any initiatives in

\textsuperscript{1106}FDA, 2007b.
response to its potential might give the message that it plans to do nothing before it is too late, as it waits for extensive safety research to be carried out. At this juncture, defining nanomaterials is commended, as the EU Cosmetics Regulation has done, because it will help industry and regulators in identifying which specific safety assessments might be required. This will identify a general class of materials for attention, whether they are benign or hazardous. Nanomaterials have many properties not shared by their larger-scale counterparts, some of which have safety implications. There are a rising number of cosmetics containing nanomaterials on the market. Engineered nanomaterials are varied but they all have nanoscale structures which alter their other properties. Because of this, size is therefore the most appropriate consideration to base a regulatory definition on.

For labelling of nano-cosmetics, although the case of GMF has always been cited for any new technology, labelling of nano-cosmetics also gives more benefit than disadvantages. Arguments may be made that the inclusion of nano-scale materials labels should not warrant additional scrutiny. Some consumers are not interested in the absolute mass or percentage, just the information that the product contains or is made through the use of that technology. Even if they are interested, will they be able to process the information? Regulators are needed to make decisions, which is why regulation is necessary. However this information is significant and essential for risk evaluation. Finally nano-cosmetic notification, as in the EU Cosmetics Regulation is necessary in order to let the consumer identify that a nano-product should be handled or disposed of in a certain way – and should therefore appear as a health and safety warning.

In short, changes in the EU Cosmetics Regulation as regards to nano-cosmetic provision are preferable due to the above reasons, compared to the USA’s approach of ‘wait and see.’ In fact, the American position is understandable, as it is no different to their cosmetics safety regulation in general as explained throughout the thesis. However, precaution is better than reparation, because some of the scientific research has proven than despite the good that nanotechnology brings, there are also certain effects. The bad effects may not be seen now but it is better to prepare early. As for Malaysia, it is preferable that it adopts the EU Cosmetics Regulation approach since nano-cosmetics are addressed in that Regulation. What has been adapted from the EU practice has served Malaysia well, and so the Regulation promises to bring even greater benefits.
Chapter 8: Conclusion

8.1 Consumers, cosmetics and their safety

Consumer products are vast and heterogeneous, with new, more technologically advanced ones being introduced every day. Cosmetic products are among the consumer products that are most popular and this is evidenced by their increasing sales. Now, cosmetics have become a necessity in people’s lives. Although not everybody wears lipstick or eye shadow, most people use toothpaste, deodorant, and skin moisturisers as a matter of course. It is now no longer the case that people need to have particular reasons for buying all sorts of other personal care products. This sort of consumption is different to that seen with pharmaceuticals, which people only normally buy when they are sick or need some treatment. This shows how important cosmetics/personal care products have become in peoples’ lives. Many people thought that they are very safe because they are rarely associated with problems.

However this is not always the case. There are also regular reports of products that are hazardous/unsafe that cause injuries to consumers. Regulation is needed to safeguard their safety. It has been explained that pharmaceutical products are inherently more dangerous and their effects are usually more lethal. As for adverse effects from cosmetics, these tend to be overlooked or at worst particular products avoided for a particular skin type.

Every region has its own beauty trends; among women in Malaysia, the use of whitening products is very popular. Fairer skin, according to them, looks better than darker skin. Illegal substances have been put in many whitening products available in Malaysia. Although these are only examples of dangerous cosmetics, such scenarios cannot be eliminated without regulatory/government intervention. In addition, in Malaysia, very few consumers use civil liability to claim their rights. Therefore, there is no other way to ensure the safety of consumer products than to have regulators intervening. The EU and the USA on the other hand, are renowned for their abilities to handle safety regulation of consumer products. It is thought that the EU offers consumers a better deal in terms of product/cosmetics safety regulation than its American counterpart. The USA however, has a great tradition of cases of product liability which often involve a lot of compensation for the consumer. This provides an incentive for the product manufacturers to produce safer products; as well as an incentive to keep their reputation intact.
8.2 Prior approval is not suitable for regulating cosmetic products

In implementing an ideal safety product regime, regulatory intervention plays an enormous role. The type of regulatory intervention depends on the type of products. For cosmetic products, it has been explained that cosmetics are comprised of formulations from specific combinations of ingredients or compositions of mixtures of substances. Cosmetic products require pre-market intervention. However, the intervention does not necessarily mean that prior approval is necessary for this type of product. This thesis has explained that prior approval is not suitable in all of the three jurisdictions compared. The previous cosmetics registration scheme practised in Malaysia shows that such systems can be burdensome and unsuitable for cosmetics. That is why Malaysia has now replaced this system with a more efficient one.

It has been analysed that the system of pre-approval for cosmetics is onerous for the following reasons. First, registration delays the launch of cosmetics that change quickly in line with developments in technology and/or fashion. For example, the practise of cosmetic registration on Malaysia earlier took between 4-6 months before the products could be approved, while the current notification process only takes not more than 2 weeks after the application has been made. Second, the exercise of prior approval does not prevent fraud or stop illegal products reaching the market. Lastly, time-consuming procedures and high-registration costs imply higher costs for companies and consequently more expensive prices must be borne by consumers.

However, with regards to the notification system which has been practise in the current system for Malaysia is suitable for Malaysia and the coming EU regulation. This is because notification system does not reach the stage of needing to be approved and need license prior to producing cosmetics, it serves to help the regulator/cosmetic authority in the monitoring the products together with the cosmetic producers. It also helps to detect any reports/adverse effects on cosmetic. In other words, the burden of safety is still on the shoulder of cosmetic producer/manufacturer.
8.3 The EU, the USA and Malaysia

It is recapitulated that the primary purpose of cosmetic regulations in all three jurisdictions is to ensure the safety of cosmetic products and to avoid adverse effect on consumer health. From previous discussions, the significant differences are mainly between the EU and Malaysian systems on the one hand compared with that of the American system on the other. Both the EU and Malaysia have control over their cosmetics safety through legislation, that is, through their Cosmetics Directives. For Malaysia, although the model for their cosmetics safety regulations is from the EU, in which similar framework had been taken especially through certain substantive elements of law and provisions adapted from the EU Cosmetic Directive, there are differences as far as procedures are concerned, for example the exercise of product notification and certain additional labelling requirements. Between the three, the most different regulatory framework for cosmetic is the USA. Contrary to the EU and Malaysia that use public regulation, the American system has depended heavily on the cosmetics industry to regulate itself in ensuring cosmetics safety and has fostered a self regulatory regime for their cosmetic products. While the EU's cosmetic safety structure are considered extensive, the USA's system has been termed the most 'liberal' compared to the other two jurisdictions.

This thesis has found that all three jurisdictions share some similarities. The responsibility for the safety of cosmetic products lies with manufacturers. It is the guiding principle, since, being the manufacturer they are the party that deals with the product from the very beginning of its formulation. The second similarity is that manufacturers of cosmetic products in these jurisdictions do not require prior approval before marketing cosmetic products on the market. That means, no product registration is required. Third, all of these jurisdictions also impose post-marketing obligations activities that are aimed at monitoring and surveillance for cosmetic products. An example of this is cosmetics recall. Despite the above similarities, there are many differences such as the definition of cosmetics, the activities conducted under pre-market as well as post market activities. There are also differences with regards to labelling and safety testing requirements. Safety assessment is one of the significant differences between the schemes in the EU/Malaysia and the USA.

1108See See L. Gagliardi and S. Dorato, 2007, supra, p. 3
safety assessment in the EU/Malaysia is required to be done by a qualified person defined in both Directives. This element confirms the safety of the finished products and its ingredients, its presentation as well as the mode of use. This element is totally absent in the USA.

As for Malaysia, although its approach to regulating the safety of cosmetics is very close to the EU model in that it follows all the safety principles in the EU Cosmetics Directive, such as the control of ingredients, the safety assessments and also labelling requirements, there are also some differences or additional requirements which have been added to suit the situation in Malaysia and in ASEAN as a whole. However, because the new system has just been introduced in 2008, it still lacks some infrastructure and resources. What is interesting is that the product notification system that is implemented in ASEAN/Malaysia has been followed by the EU in the Cosmetics Regulation, and this is being implemented in 2013. This is a testament to the fact that some processes put in place by a developing region can also be adopted by the EU. Although it is not yet known how it will fare because it comes into force in 2013, it is expected that the new system will be more efficient.

8.4 Public regulation vs self-regulation
Between the three jurisdictions, it is observed that the EU model, using public regulation has a greater control on cosmetic; in which is thought to offer the most efficient system of safety of cosmetic between the three jurisdictions whereas the USA with self-regulatory scheme places cosmetics safety under a voluntary regime and has been adopted with minimal supervision. This is attributed to the fact that the old style EU regulation in cosmetics involves three layers of safety elements for safety assurance in the EU. First, the legislation itself that requires cosmetics to be safe. Second, there is the professional safety assessor who personally signs to say the cosmetic product is safe. Third, there is the control by authorities checking on products placed on the market. Although Malaysia adopts the same regulation and is similar to the EU in that it has a three layer safety system for cosmetics, it lacks the infrastructure and resources to fully support the system as this new regulation has only recently been implemented. In comparison the USA, although having the oldest law on cosmetics, gives the FDA’s only limited statutory powers to regulate cosmetics, cosmetics are largely subject to a voluntary compliance system. It must be
noted however that in the USA, this role is possibly played by civil liability. Although the voluntary programs/system of cosmetic had always been the source of criticism, they are argued by others to be a symbol of cooperation.

In comparing between the systems, the EU system has been regarded as ‘generally more restrictive’\(^{1109}\) than the USA system of regulating cosmetics. In the EU, the cosmetic manufacturers need to show a heavier burden that their products are safe. Among the significant example is a large number of ban of certain chemical substances which have been proven by scientific studies to be dangerous for human health compared to just a few ban by the USA. The SCCP which has been mandated with the responsibility to review cosmetic ingredients has for example highlighted in its opinion that if such dangerous substances are presents in a cosmetic product either from its natural ingredients, or gained during the manufacturing process; it must be shown that the product does not pose a threat to consumers’ health.\(^{1110}\)

In addition, the amendments and technical adaptations in the EU that have been made several times mainly show the EU has exercised greater control over the cosmetic safety with the aim of protecting the environment and health of consumers. Also, even though prior approval is not required for cosmetics, cosmetic manufacturers are obliged to keep safety report file (PIF), which also include the adverse effect data, if any. This is however not a mandatory requirement for cosmetic manufacturers in the USA. The ban in the EU of the dangerous substances has demonstrated the fact that it has reinforced the concern of cosmetic safety in which its approach has been followed by many other countries. It was held that optimists believed that the ban ‘could shift corporate behaviour in American market and stoke political will to regulate.’\(^{1111}\) Until recently, there is no sign of this happening yet.

Given the fact that the EU has mandated full ingredients to be declared, together with the expiration dates, the ingredients functions, precautions to be observed, and batch numbers, the EU is noted as having a more detailed and extensive labelling requirements as compared to the USA. Lastly, the formation of


\(^{1110}\)SCCP, Opinion Concerning Request for Confirmation of the SCCNP Opinion, on Chemical Ingredients in Cosmetic Products Classified as Carcinogenic. Mutagenic, or Toxic to Reproduction According to Council directive, 15 March 2005

cosmetic database in the EU provides easy access to consumer about more information they use. In conclusion, it seems that the three layers of safety assurance exercised in cosmetics schemes means greater control over cosmetics with the aim of protecting consumer health. The three layers/elements of safety mentioned are typically provided by a regulator’s direct intervention, which is through public regulation. Certainly self-regulation is not totally unsuitable for regulating the safety of cosmetics. They can still be exercised by implementing self-regulation through a voluntary standard. Also, the EU system is more efficient because it is co-regulation, with the cosmetic industry in which has also contributed to the safeguarding safety by the industry. Therefore, public regulation, in particular as practised in the EU has been endorsed in this thesis to a much greater extent than the American one mainly because the elements of safety are greater and more stringent.

8.5 Regulating nano-cosmetic

The EU at the moment is moving forward with new legislation that will specifically govern nano-cosmetics – a first anywhere in the world. The main reason for the different approach can be attributed to the fact that nano-products pose unique risks and challenges. It seems that the USA is unlikely to undertake any major new statutory revisions to address nanotechnology currently, unless, as Marchant et al.1112 claim, there is some major incident or disaster. This possibility is mirrored in the history of USA environmental law, where it took a big incident, such as rivers burning due to oil pollution, for legislators to enact new, more stringent legislation. The EU is at the forefront not only because it has a specific reference to the term nano in its legislation but because it defines it and requires nanoproducts to be appropriately labelled. Despite the fact that the EU thought that labelling nano-cosmetics was essential, it has been argued that labelling of cosmetics is unnecessary and inappropriate due to the fact that there are no known nanomaterial hazards that people should be warned about. In addition, it has also been claimed that simply identifying a cosmetic as a nanoproduct seems meaningless given the variety and range of existing and anticipated nanotechnology products. It has also been mentioned that a moratorium has been called for by some agencies who believe that these materials should be considered hazardous until proven otherwise. This

moratorium has been considered inappropriate by some given that the potential benefits from nanotechnology applications appear to be significant. Although a voluntary programme might be useful, as in the USA, many non-governmental organisations are dissatisfied with such an approach, and most importantly public safety is not assured by a voluntary programme. At the moment, the existing frameworks of the mentioned jurisdictions are seen as inadequate to regulate nanomaterials and nano-cosmetics in particular. However, the EU should be commended for initiating the implementation of a new cosmetic regulation that includes nanomaterials. Labelling of nano-cosmetics for example, although argued as unnecessary and inappropriate due to the fact that there are no known nanomaterial hazards that people should be warned about, will certainly benefit industry and oblige it to engage with and inform consumers from the outset by declaring the use of manufactured nanomaterials. This is especially important with products that are becoming essential for consumers such as cosmetics.

8.6 What did Malaysia learn from its adoption of the EU scheme?

It seems that the success of the EU has inspired Malaysia (ASEAN) to follow suit. Both use public regulation in determining the safety of cosmetics in their regions. Malaysia, as a developing nation, has benefited from the adoption of the EU system through the harmonisation of cosmetics regulation between ASEAN countries. As with any newly introduced system, Malaysia has experienced some setbacks and encountered certain problems. The problems that have been identified are due to a lack of resources, structure, technical facilities and qualified personnel. Despite the teething problems, however, it seems that the greatest benefit taken from EU involvement has been cosmetics harmonisation throughout the ASEAN region. This has not only provided benefits for consumer safety and trade, but also for governments as they have not had to undertake a lot of research or spend money developing the regulation because it has already been done by the EU. A significant benefit has been the importation of the scientific evaluation by the SCCP, which has been adapted into ASEAN/Malaysia. It may have been difficult to set up the ASEAN/Malaysia scheme had this work not already been done, given the lack of resources, and lack of scientific expertise as mentioned. In addition, there has been a programme called APRIS (ASEAN-EU Programme for Regional Integration Support) to assist ASEAN in strengthening post-market surveillance by providing technical
assistance and training in respect of product safety, drafting of Product Information Files and product liability for national regulatory authority and the cosmetics industry. Although there is still much room for improvement, a great deal has been learnt from the EU. More importantly, this borrowing has benefited consumers, insofar as safety is concerned, because of the common and standard safety assessments and the responsibility of safety now being placed on the manufacturers. Consumers can also enjoy more products due to the elimination of trade barriers through free movement and cooperation between member states.

Finally, it is admitted that undertaking the research for cosmetics safety has not been easy. This is because it involves analysing the theory surrounding product safety regulations and how it relates specifically to cosmetics to determine where cosmetics stand in the larger picture of general safety regulations. Investigating the existing legal mechanisms in the cosmetics safety framework is even more difficult because this thesis compares three different jurisdictions. There was plenty of material to work from for the EU and the USA, however this was not the case with Malaysia. This lack of source material and previous studies on this for Malaysia has been the greatest challenge. Despite such challenges, it is hoped that this thesis, above all, has achieved its primary objective; to determine whether cosmetics safety regulations are adequate and efficient for protecting the safety of consumers.
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