SGS SEMINAR
GOING GLOBAL
IN-COSMETICS 2016
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GOING GLOBAL

Moving into new markets is something companies often think about but do not always know how to go about. This seminar covers some of the regulatory aspects of USA, China, ASEAN and Gulf States. It aims to cover some of the special requirements and pitfalls of selling products in these markets. The seminar will also look at testing requirements and will give specific examples of different products and how they are regulated in each market.
Regulation of cosmetics can be broadly split into 2 categories:

- **Post market surveillance**
  - Europe, United States of America, Canada, Australia, ASEAN

- **Pre-market testing**
  - China, Gulf States
UNITED STATES OF AMERICA
USA - OVERVIEW

- Food, Drug and Cosmetic Act
- Fair Packaging and Labelling Act
- Food and Drug Administration (FDA) regulates cosmetics at a federal level
- Some US states have their own legislation in addition to federal legislation
FOOD AND DRUG ADMINISTRATION (FDA)

- FDA does not pre-approve cosmetics before they are sold to the public
- Companies do not have to file health and safety data on cosmetic ingredients
- FDA does not have authority to order a recall of dangerous cosmetic products
- Premarket safety testing of cosmetic products is not required
- Colours are regulated by FDA
Cosmetics are "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" [FD&C Act, sec. 201(i)].

Cosmetics include skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, and deodorants.
FD & C Act defines a drug as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].

Some products are defined as both cosmetics and drugs.
- Antidandruff shampoo
- Toothpastes containing fluoride
- Antiperspirants
- Moisturisers and makeup products which have a sun protection claim
Drugs must either receive pre-market approval from FDA or conform to a monograph for a particular drug category. The monographs specify conditions whereby the over the counter (OTC) drug ingredients are generally recognized as safe and not misbranded.

There are OTC monographs for:
- Acne medications
- Treatments for dandruff, seborrheic dermatitis, and psoriasis
- Sunscreens
- Regulated by FDA through monographs
- Soap is exempt from the provisions of FD & C Act
- Soap products contain alkali salts of fatty acids
- The alkali salts of fatty acids must give the product its detergency properties
- Product has to be labelled and represented solely as soap. [21 CFR 701.20]
- Soap products are regulated by the Consumer Product Safety Commission
Plastic microbeads are defined as plastic particles that are used to exfoliate or cleanse the body and are less than 5mm in size.
Minnesota

- Minnesota has banned formaldehyde in children’s personal care products. The ban applies to the use of formaldehyde in cosmetic products for children under eight years of age. Formaldehyde releasing preservatives are permitted providing the free formaldehyde level is not greater than 0.05%.

Washington State

- Washington State has adopted the Children’s Safe Product Act (CSPA – Chapter 70.240 RCW), which requires manufacturers of children’s products including personal care products sold in Washington State to report to the state if their product contains a Chemical of High Concern to Children. Chemicals of high concern include methylparaben, ethylparaben, propylparaben, butylparaben, and 1,4-dioxane.
California

■ Proposition 65

■ Safe Drinking Water and Toxic Enforcement Act of 1986 better known as Proposition 65,

■ Enacted by the State of California to protect its citizens and the state’s drinking water from chemicals known to cause cancer, birth defects or other reproductive harm.

■ Proposition 65 requires that a list of chemicals known to cause cancer or birth defects or other reproductive harm is published. The list is updated at least once a year and includes:
  • Cocamide DEA
  • Titanium dioxide (airbourne, unbound particles of respirable size)
  • Toluene
  • Benzophenones
  • Talc containing asbestiform fibres.
California

- **Proposition 65**
- Some cosmetic products may contain impurities such as 1,4-dioxane, ethylene oxide, diethanolamine and lead which are also on the proposition 65 list.
- The courts in California determine whether these chemicals are permitted in cosmetic products sold within the State and whether labelling is required to warn of their presence
California Safe Cosmetics Act

In 2005 the State of California passed the California Safe Cosmetics Act that requires manufacturers of cosmetics to disclose to the state any product that contains an ingredient that has been identified as causing cancer or reproductive toxicity.
THE ANTIPERSPIRANTS AND DEODORANTS REGULATION

- Sets volatile organic compound (VOC) limits for antiperspirants and deodorants.

California Consumer Products Regulations

- Sets volatile organic compound (VOC) limits for consumer goods. Includes:
  - Hair mousse
  - Hair shine
  - Hair finishing spray
  - Hair styling product: aerosol and pump spray
  - Heavy duty hand cleaner or soap
  - Nail polish remover
  - Personal fragrance products
  - Shaving cream
  - Shaving gel
  - Temporary hair colour - aerosol
CANADA
Cosmetic products in Canada are regulated by the Food and Drugs Act and Cosmetic Regulations.

- Food and Drugs Act and the Cosmetic Regulations
- Consumer Packaging and Labelling Act
- Consumer Packaging and Labelling Regulations
- Hazardous Products Act
- Consumer Chemicals and Containers Regulations

Labels should contain both French and English apart from the ingredient names.

Manufacturers and importers must notify Health Canada within 10 days of selling a cosmetic product in Canada.
Ingredients that are restricted or prohibited for use in cosmetics are listed on the cosmetic ingredient hotlist.

In Canada fatty acid ethanolamines such as cocamide DEA are permitted for use in cosmetics. Formaldehyde is permitted for use in nail hardeners, oral cosmetics and non oral cosmetics.

The use of ethoxylated ingredients is permitted in Canada providing the 1,4-dioxane concentration is low.
Heavy Metals

- The presence of heavy metals in cosmetics is permitted providing they are at levels that are technically unavoidable. Health Canada has published guidance that states that heavy metal impurities are deemed to be technically avoidable when they exceed 10 ppm for lead, 3 ppm for arsenic, 3 ppm for cadmium, 3 ppm for mercury, and 5 ppm for antimony.

Microbeads

- Canada has banned microbeads in rinse-off cosmetics.
AUSTRALIA
Cosmetic products are regulated as industrial chemicals under the Industrial Chemicals (Notification and Assessment) Act 1989.

All importers and manufacturers of cosmetic products must register with National Industrial Chemicals Notification and Assessment Scheme.

**Cosmetic Standard 2007**

Sunscreen products, anti-bacterial products, products for the care of the teeth and mouth, and anti-dandruff products must be compliant with the Cosmetics Standard 2007.

**Ingredients**

Ingredients must appear on the Australian Inventory of Chemical Substances (AICS).

Extracted natural substances do not need to be listed on Australian Inventory of Chemical Substances as they are deemed to be on the Australian Inventory of Chemical Substances.
New Chemicals

If an ingredient is not listed on the Australian Inventory of Chemical Substances then it is deemed to be a new chemical. Companies should apply for a certificate or permit by submitting a notification to NICNAS.

Labelling

Cosmetics must be labelled in accordance with the Trade Practices (Consumer Product Information Standards (Cosmetics) Regulations 1991.

Microbeads

Microbeads to be phased out on a voluntary basis by the end of 2017.
Cosmetic Sunscreens

There are two types of sunscreen in Australia. Cosmetic sunscreens contain an ingredient which has sunscreen properties but the primary purpose of the product is not to provide protection from the sun. Cosmetic sunscreens are regulated as cosmetics by National Industrial Chemicals Notification and Assessment Scheme.

Therapeutic Sunscreens

Therapeutic sunscreens are regulated as therapeutic goods by Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations 1990. They include sunscreens used for protection from ultra violet (UV) radiation which have a sun protection factor (SPF) of 4 or more, insect repellents which have a sun protection factor of 4 or more and moisturisers with a sun protection factor greater than 15.
ASEAN COUNTRIES
The ASEAN countries are Brunei Darussalam, Cambodia, Indonesia, Lao People’s Democratic Republic, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam.
ASEAN COUNTRIES

Notification

The company or person responsible for placing the cosmetic on the market must notify the regulatory authority in each country before the product is placed on the market. Product notifications can only be made by individuals or companies who are registered to do business in that country. Product registration is valid for 5 years.

ASEAN Cosmetics Directive

- The ASEAN cosmetic directive contains lists of substances which are not permitted in cosmetics; substances which are restricted; colorants; preservatives and permitted sunscreen filters.
- The regulatory authority carries out post-market monitoring and surveillance to ensure compliance with the directive.
CHINA
Cosmetics are classified into two categories “non-special purpose cosmetics” and “special purpose cosmetics”.

“Non-Special Purpose Cosmetics” which refers to cosmetics with no medicinal effects such as hair care products, skin care products, make-up, lip care products etc.

“Special Purpose Cosmetics”, which refers to cosmetics with special purpose such as products for hair growth, fitness, breast shaping, hair dye, hair perm, etc.
The State Food and Drug Administration (SFDA) are responsible for approving cosmetic and beauty products.

The SFDA have published a list of 8783 ingredients which are permitted to be in cosmetics used in China.

Ingredients which are not listed in the Inventory of Existing Cosmetic Ingredients in China must be registered with the SFDA.

Toxicological testing and safety assessment are part of the registration process.

Very few new ingredients have been registered with SFDA.
Companies importing into China for the first time will need to appoint a Chinese legal company to carry out the registration process for them. All imported cosmetic products must obtain pre-market registration with the Chinese State Food and Drug Administration.

Imported cosmetic products are tested for microorganisms, physical chemistry including heavy metals, toxicology, human safety and efficacy as part of registration process.

It can take 9 – 12 months to get an imported cosmetic product to market in China.
GULF STATES
Gulf States

- The Gulf States are Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates and Yemen.
United Arab Emirates

- United Arab Emirates have their own standards for cosmetics. Standards are issued by Emirates Authority for Standardization & Metrology (ESMA).

- A responsible person based in the United Arab Emirates needs to be appointed. This can be the manufacturer’s representative or the importer.

- Products must be manufactured in accordance with UAE.S GSO ISO 22716 or any GMP approved by ESMA.

- Products must comply with UAE.S. GSO 1943.

- A UAE trade license is required. The certificate needs to be collected in person from ESMA office.

- A cosmetic product safety report is required for perfume products.
Saudi Arabia

- All cosmetics must be licensed through “the Electronic System of Cosmetic Notification” which is available through the Saudi Food and Drug Authority (SFDA) website.

- Warehouse licenses for cosmetics manufactured outside Saudi Arabia and manufacturing licenses are required.

- To ensure clearance of cosmetic goods at customs a mandatory Certificate of Conformity/SASO certificate must be obtained before the goods are sent, these certificates can only be issued by a SASO mandated inspection agency.

- Test reports are the most important documents exporters will need to obtain a certificate of conformity. Test reports must not be more than 6 months old and from an accredited laboratory.

- Typical tests for surfactant products include tests for pH; surfactant content; heavy metals; nitrosamine; 1,4-dioxane; lard and lard derivatives; and bacteria, yeast and mould and pathogens

- Creams and lotions will need to be tested for fatty matter.
1. Is my product a cosmetic? Definition of cosmetic differs from country to country.

2. Will I need to appoint a responsible person / legal representative to register my product or act on my behalf?

3. Are any of the ingredients in my product classified as carcinogenic, mutagenic, or reprotoxic?

4. Are some of the ingredients prohibited in countries / states that I wish to sell my products in e.g. cocamide DEA in California?

5. Keep 1,4-Dioxane concentration as low as possible and less than 10 ppm.

6. Do I need ISO 22716: 2007 (GMP)?

7. Plan for the future by formulating products for more than one market.

8. Allow enough time for regulatory compliance.

9. Budget for testing of products. Generally it costs more to get products to market when pre-market testing is required.

10. Consider limiting the number of products you launch on to a new market.