Going global: formulating for different markets

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This article aims to give an overview of how cosmetic products are regulated in the US, Canada, Australia, and ASEAN countries. These countries were chosen as they regulate cosmetics through post market surveillance and not through pre-market testing. We have tried to highlight some of the similarities and differences between these regulations and Regulation (EC) No 1223/2009. The final part of this article looks at what you may need to consider when formulating for these markets.

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Global personal care markets vary considerably due to ingredient regulations.

The US

In the US the two most important laws that apply to cosmetics are the Food, Drug and Cosmetic Act and Fair Packaging and Labelling Act. The Food and Drug Administration an agency of the US government regulates cosmetics on a federal level. Some US states have also enacted state legislation that applies to cosmetic products sold within that state.

Cosmetics and their ingredients are not required to be approved by the Food and Drug Administration (FDA) before they are sold to the public and the Food and Drug Administration does not have the authority to require manufacturers to file health and safety data on cosmetic ingredients or to order a recall of a dangerous cosmetic product. Premarket safety testing of cosmetic products is not required. The Food and Drug Administration does regulate the use of colours in cosmetics. Some products such as antidandruff shampoo, toothpastes containing fluoride, antiperspirants, and moisturisers and makeup products which have a sun protection claim are defined as both cosmetics and drugs and have to meet the requirements of both. Sunscreens are classed as over-the-counter drugs.

US federal legislation

The Microbead-Free Waters Act of 2015 prohibits the manufacture and introduction to the market of rinse-off products containing plastic microbeads. The intention is to phase out the manufacture of such products by 1 July 2017 and prohibit sales by 1 July 2018. The act amends Section 301 of the Federal Food, Drug, and Cosmetic Act and applies to rinse-off cosmetics including toothpaste. For non-prescription drugs that are rinse-off cosmetics manufacture must cease by 1 July 2018 and they must be removed from sale by 1 July 2019. Plastic microbeads are defined as plastic particles that are used to exfoliate or cleanse the body and are less than 5 mm in size.

The Cosmetic Modernization Amendments Bill of 2015 proposes to amend the Federal Food, Drug and Cosmetic Act to require cosmetic manufacturing establishments and cosmetic products to be registered with the Food and Drug Administration within 60 business days of the first sale of the product. Manufacturers would be required to submit a statement containing the brand names, cosmetic category, ingredients list and contact details. Serious or unexpected adverse effects would need to be reported to the Food and Drug Administration within 15 days.[1]

US state legislation

In the absence of federal legislation, some US states have their own requirements. Minnesota has banned formaldehyde in children's personal care products. The ban applies to the use of formaldehyde and formaldehyde-releasing preservatives in cosmetic products for children under eight years of age. 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.[2]

In 1986 the Safe Drinking Water and Toxic Enforcement Act of 1986, better known as Proposition 65, was 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.[3] 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. Chemicals that are listed in the proposition 65 list include: cocamide DEA, titanium dioxide (airbourne, unbound particles of respirable size), toluene, benzophenone, and talc containing asbestiform fibres. 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 have determined whether these chemicals are permitted in cosmetic products sold within the State and whether labelling is required to warn of their presence. The antiperspirants and deodorants regulation sets limits for volatile organic compounds contained within antiperspirant and deodorant products.[4]

Canada

Cosmetic products in Canada are regulated by the Food and Drugs Act[5] and Cosmetic Regulations.[6] Cosmetic products sold in Canada must be labelled in accordance with the Food and Drugs Act and the Cosmetic Regulations; the Consumer Packaging and Labelling Act[7] and the Consumer Packaging and Labelling Regulations; and the Hazardous Products Act and the 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.[8]

Australia

In Australia cosmetic products are regulated as industrial chemicals under the Industrial Chemicals (Notification and Assessment) Act 1989. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) was established to assess the risk of industrial chemicals. All importers and manufacturers of cosmetic products must register with National Industrial Chemicals Notification and Assessment Scheme. Sunscreen products, antibacterial products, products for the care of the teeth and mouth, and antidandruff products must be compliant with the Cosmetics Standard 2007. Ingredients used in cosmetics sold in Australia 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. 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.[9] Cosmetics must be labelled in accordance with the Trade Practices (Consumer Product

Information Standards (Cosmetics) Regulations 1991.

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 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. 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 five years. The company or person responsible for placing the product on the market must ensure that the product complies with the ASEAN cosmetics directive and will not cause harm to human health when the product is used under normal and foreseeable use. The regulatory authority carries out post-market monitoring and surveillance to ensure compliance with the 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.

Europe

In the European Union cosmetics have to be registered on the cosmetic product notification portal and then can be placed on the market providing the requirements of Regulation (EC) No 1223/2009 are met. A responsible person within the European Union has to ensure that a product is safe and complies with EU legislation. Testing such as stability, microbiological testing, preservative efficacy testing, and heavy metal testing is done so that a cosmetic product safety report can be written. Testing is also required to substantiate any claims being made for the product. The presence of small quantities of prohibited substances such as heavy metals and 1,4-dioxane are permitted provided their presence in the product is technically unavoidable and the product is safe for human use.[10] Regulation (EC) No 1223/2009 permits the use of substances classified as CMRs providing the requirements of Article 15 of the regulation are met.

Formulating for different markets

When formulating for different markets it is important to understand what the consumer wants. It is also important to understand how the different markets are regulated. Many companies have existing products which they want to sell in different countries. It is worth considering when formulating a new product the countries and regions that your product could be sold in and to formulate the product so that it can be sold accordingly.

When formulating for the United States of America it is worth considering whether your product needs to comply with both federal and state legislation and will be sold in all 50 states. If the product is going to be sold in California then checking the proposition 65 list is essential. It is also important to consider if any substances listed on proposition 65 could be present as an impurity. Testing any product that contains sodium laureth sulfate or an ethoxylated ingredient for 1,4-dioxane is strongly recommended. The courts in California have decided that cosmetic products that contain 10 ppm or more of 1,4-dioxane must have a warning on the label.[11] Some ingredients such as cocamide DEA which are permitted in the European Union are prohibited in California.

All colours used in cosmetics in the United States of America have to comply with Food and Drug Administration requirements. There have been a number of cases of cosmetic products not being allowed to enter the country because colours have been deemed to be adulterated. If formulating coloured cosmetics for sale in the European Union and US it would be worth using colours that meet the requirements of both the Food and Drug Administration and Regulation (EC) No 1223/2009.

In the US, sunscreens are over the counter drugs. The number of sunscreens permitted in the US is less than in the European Union and some of the combinations of sunscreens permitted in Europe are not permitted in the US.

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. This is similar to how Regulation (EC) No 1223/2009 permits the use of formaldehyde. It is worth noting that formaldehyde has been classified as Carc. 1B and Mut. 2 by European Commission Regulation (EU) No 655/2014. This classification has been adopted from 1 January 2016 and may affect how formaldehyde is regulated in the future.

The use of ethoxylated ingredients is permitted in Canada providing the 1,4-dioxane concentration is low. 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.[12]

Regulation (EC) No 1223/2009 requires that a cosmetic product safety report is written for every cosmetic product that is placed on the market within the European Union. It would be worth considering writing a toxicological risk assessment for products that are being sold outside of the European Union as part of due diligence.

Conclusion

This article has looked at the regulatory requirements for cosmetics in the US, Canada, Australia, and ASEAN countries. By understanding the regulatory requirements of different countries, states or regions it may be possible to formulate products that can be sold in more than one market. PC

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