

International Regulatory Challenges in the Cosmetics Industry

Discover Global Markets: Healthcare and Life Sciences

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Personal Care  Products Council
Committed to Safety,
Quality & Innovation

Outline of Today's Talk

- **Claims**
- **Global Trends in the Cosmetic and Personal Care Industry**

The Personal Care Products Council

- Industry trade association with >600 member companies
- Manufacturers and distributors
- Suppliers of ingredients, raw materials, packaging, and other services
- Majority small companies

By creating a productive business and regulatory environment, enable members to develop and sell safe, quality and innovative products that help consumers live better, healthier lives and to enhance the reputation of the industry.



Sound Science



Modernized Legislation



Global Access

Claims in the Personal Care Products Industry

Countries have different regulatory frameworks for claims:

- **Lists of acceptable claims**
- **Lists of unacceptable claims**
- **Requirements to substantiate claims with scientific or other evidence**

Regulation No. 655/2013 - European Commission's common criteria for the justification of claims used in relation to cosmetic products

European Cosmetics Regulation No. 1223/2009 regulates cosmetic claims in Article 20:

“In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.”

Regulation (EU) No. 655/2013

- In Article 20: the Commission shall adopt a list of common criteria for claims which may be used in respect of cosmetic products.
- Broad in scope – not just for claims on packaging, but all advertising
- Guidelines, published July 2013, are also very general
- Recital 51 referred to defining common criteria in relation to specific claims

Common Criteria of Regulation (EU) No. 655/2013

Legal compliance

Truthfulness

Evidential support

Honesty

Fairness

Informed decision-making

Regulation (EU) No. 655/2013

- Unlike in the food sector, the Commission did not wish to develop a list of *specific* claims
- Some Member States want clarification regarding some specific claims:
 - 'Free-from'
 - Natural and/or 'organic'
 - Health-related claims (ex.: hypoallergenic)

Resources

Commission Regulation (EU) No 655/2013:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:190:0031:0034:en:PDF>

Guidelines to Commission Regulation (EU) No 655/2013:

http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/guide_reg_claims_en.pdf

Consumer Protection from Unfair Trading Regulations:

<http://www.legislation.gov.uk/uksi/2008/1277/contents/made>

Business Protection from Misleading Marketing Regulations:

<http://www.legislation.gov.uk/uksi/2008/1276/contents/made>

Latin America

- **MERCOSUR (the Latin American Common Markets: Brazil, Argentina, Paraguay, & Uruguay)**
- **Bolivia, Chile, Colombia, Costa Rica, Ecuador, Guatamala, Honduras, Peru, Venezuela**
- **Wording is within definition of ‘cosmetic’ in ANMAT regulations:**
“These products must not claim any therapeutic activity.”
- **Claims in which specific testing is implied must be substantiated**

Latin America

Brazil

- **ANVISA, the Brazilian Health Surveillance Agency, does not review advertising**
- **Decree No. 79.094/77, Article 93 has language prohibiting deceptive advertising and labeling**
- **Article 37 of the *Brazilian Consumer Protection Code* prohibits any advertising that misleads the consumer (includes direct mail and tele-marketing)**

Asia Pacific

Japan

- **Amendments in the range of cosmetic efficacy No. 1339 of Schedule 1 drug from December 28, 2000.**
- **Lists 57 acceptable claims**

Korea

- **Consumer perception claims must be tested by an independent laboratory**
- **Data-driven claims can be tested internally**

Asia Pacific

ASEAN

ACD Article 7:

- **Member States are responsible for ensuring that product claims comply with the ASEAN Cosmetic Claim Guidelines (Appendix III)**
- **Products are determined to be either “cosmetic” or “drug” based on two factors:**
 - **Composition of the product, and**
 - **The proposed use of the product**

China

- From the recent “Cosmetic Supervision and Administration Rules (CSAR)” (draft for comments) - Article 43 (Claim Management).
- “The claims regarding the function of cosmetic products should be supported by abundant experimental evidence or evaluating data.”
- More clarification is sought by industry

Taiwan

- **Revising the Cosmetics Act**
- **Have a list of claims (in Chinese) on their website:**

<http://www.fda.gov.tw/upload/133/2013062115394262284.pdf>

Canada

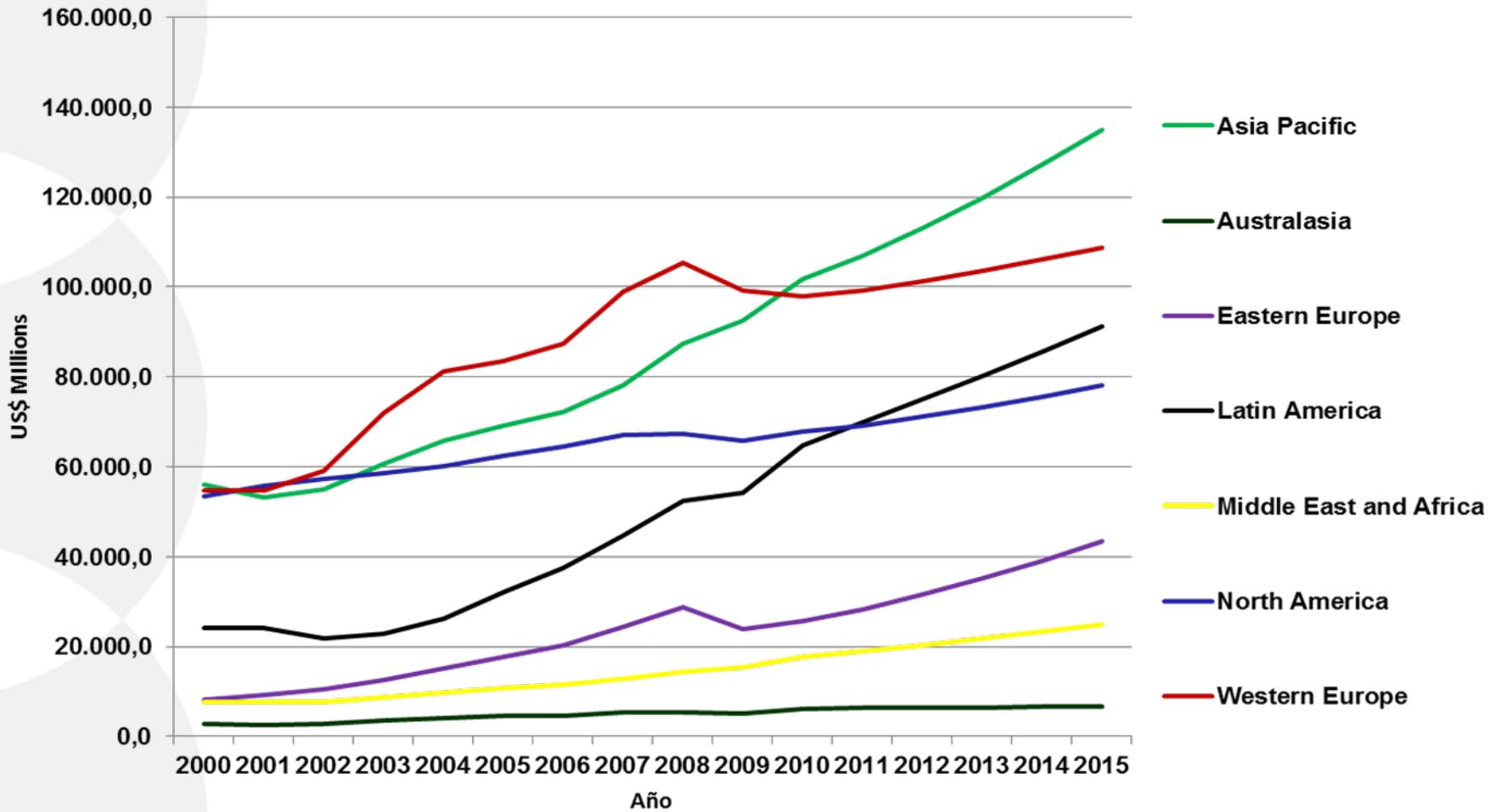
- *ASC Guidelines for Cosmetic and Non-therapeutic Advertising and Labelling Claims for Cosmetic and Nonprescription Health Products including Natural Health Products (Guidelines)*
- **New format: streamlined and easier to use**
 - Therapeutic/Health Claims column and Cosmetic/Non-therapeutic Claims column
- **Non-therapeutic claims are cosmetic claims**
- **Exclusion of a claim does not infer it is unacceptable to H.C.**

<http://www.adstandards.com/en/Clearance/Cosmetics/Guidelines-for-the-Nonprescription-and-Cosmetic-Industry.pdf>

Global Trends

The cosmetics and personal care products industry is a truly global industry.

Latin America is the third Regional Market in Cosmetics



Fuente: Euromonitor, incluida la proyección 2011-2015

Emerging Markets trends

Brazil and China show most dramatic market growth

- **Brazil:**
 - **Middle class driving sales**
 - **Growth in color cosmetics, fragrances, oral and skincare**
 - **Fastest growth: mass fragrance sales; deodorants**
 - **Direct sales = approx. 1/3 of all sales**

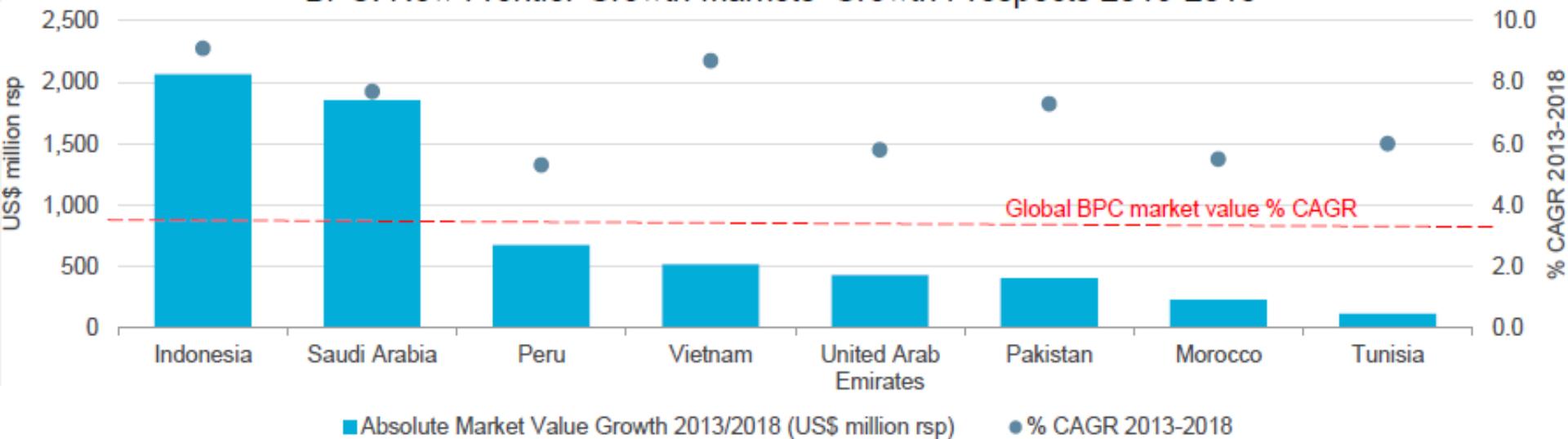
Emerging Markets trends

- **China:**
 - **Rapid economic development: fast-growing middle class and internet network**
 - **4 major segments in the cosmetics market: skincare, haircare, color and fragrance**
 - **Skincare considered an investment, with whitening and anti-aging most important**
 - **Cultural perceptions of color cosmetics and fragrances**

Sales by Segments

- **Mass beauty segment accounts for 72% of total sales**
- **Premium segment accounts for 28%**
 - **Developed markets: US, Japan, France**

BPC: New Frontier Growth Markets' Growth Prospects 2013-2018



* Source: Euromonitor 2013

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Concluding thoughts

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www.personalcarecouncil.org