Cosmetic Safety Evaluation and its Relevance to the African Consumer

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Cosmetics! How defined?

• EU definition
  – A "cosmetic product" shall mean any substance or mixture 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 (http://www.ctpa.org.uk/content.aspx?pageid=304)

• US definition
  – The **Federal Food, Drug, and Cosmetic Act** (FD&C Act) as "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)]. Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance intended for use as a component of a cosmetic product. (http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm)

• Canadian definition:
  – "any substance or mixture of substances, manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes"(http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/psp-psp/cosmet-eng.php)
Any Substance or Mixtures (mostly chemicals)
Placed or used on external parts of the body (or around body cavities)
With the purpose of cleansing, beautifying, promoting attractiveness, or altering the appearance or removing odors (odours)
Not said but important
- Use/application will not diagnose treat or prevent diseases
- Mechanism of action is not to alter the biology
General Classification

Standard International Trade Classification (SITC)

- Perfumes and toilet waters
- Beauty, make-up & skin-care prep, manicure etc.
- Preparations for use on the hair
- Preparations for oral or dental hygiene,
- Personal toilet, shaving, bath etc

- Ref: http://www.foreign-trade.com/reference/hscode.cfm?code=33
Relevance of cosmetics today

• Part of Fast Moving Consumer Goods (FMCG)
  – Business size: Globally estimated $265 billion in 2017 with a \textit{Compound Annual Growth Rate} (CAGR) of 3.4\% over the next five years (2012-2017)
  – estimated in the US to amount to about 62.46 billion U.S. dollars in 2016
  – In Africa: expected to be worth $13.2 billion in 2017
  – consumers have been spending higher levels of disposable income on cosmetics than they had in the past

• Present every home and used by almost everyone
  – Women, Men, Adolescents Children
Safety

• What is safety?
  – freedom from harm or danger: the state of being safe. : the state of not being dangerous or harmful (www.merriam-webster.com/dictionary/safety)

• Is there absolute Safety?
• Which one of these is absolutely Safe?
  – Cars and Airplanes, Nuclear reactors, Water, Knife, Sugar, Paper

• Hazard
• A hazard is any source of potential damage, harm or adverse health effects on something or someone (Hazard and Risk: OSHA answers www.ccohs.ca/oshanswers/hsprograms/hazard_risk.htm)

• Exposure - the processes that take place at the interface between the hazardous source and the person
• Risk is the chance or probability that a person will be harmed or experience an adverse health effect if exposed to a hazard
Risk Assessment

• Is the process of identifying variables that have the potential to cause negatively impact (or injury) from an identified hazard.

Factors that influence the degree of risk include:
• how much a person is exposed to a hazardous thing or condition,
• how the person is exposed (e.g., breathing in a vapor, skin contact), and
• how severe are the effects under the conditions of exposure
Risk Assessment

Risk is the product of hazard and exposure.

1. With no cage and distance the exposure is immediate.
2. With cage and distance exposure is negligible.

everyone valued, everyone included, everyone performing at their peak...
How do we assess Exposure?

• Is there potential for Exposure?
• What is the Exposure Context?
everyone valued, everyone included, everyone performing at their peak...
How Consumers and Regulators think about the safety of our products
Exposure Assessment

Key Exposure Questions

- WHAT product category is being evaluated?
- WHO is using the product?
- WHEN is the product used?
- HOW is the product used?
- WHERE is the product used?
WHAT product is being evaluated?

- Understanding the product category is one of the first steps in developing an exposure assessment
- There are many product categories
  - A lotion or soap
  - Hand wash or bodywash
  - Direct or indirect (eg from washed clothes)
  - Secondary? (in the environment-)
WHO is using the product?

The user(s) of the product should be established as clearly as possible

- Children/Infants
- Pregnant Women
- Plant workers
- General population
- Regional Considerations?
WHEN is the product used?

Understand use patterns for product being evaluated

- Daily?
- Monthly?
- Once a week?
- Once a month?
- Once in a while?
- Lifetime?
WHERE is the product used?

 Environment
  ➢ Bathroom?
  ➢ Laundry Room?
  ➢ Outside?
  ➢ Production Plant?

 Body Site
  ➢ Head
  ➢ Whole body
  ➢ Hands & Arms
HOW is the product used?

Understand the intended use of the product may need enlist the help of PDD

- Applied directly
- Leave-on
- Rinse-off
- Ingested
- Indirect exposure
- Route(s) of exposure
Additional Exposure

- **Unintended use**
  - Abuse-huffing of aerosol products, ingestion of alcohol containing products.
  - Ingestion of non-food products (pica, confusion with a food or drug product)
  - Ingestion by children
  - Eye exposure (cleaning products, antiperspirant)
Government Regulations

• All cosmetic and personal care product manufacturers are required by Govt laws to demonstrate the safety of their products and ingredients before they go to market –
  (http://www.cosmeticsinfo.org/science-of-safety#sthash.zA8Skfzt.dpuf)

• The United States and European Union: Strictly Regulate Cosmetic Safety
  – The United States (US) and European Union (EU) both work to ensure the safety of cosmetics for consumers through rigorous regulation.
  – (FDA) which has been granted broad regulatory authority under the federal Food, Drug and Cosmetic Act, enacted in 1938.
  – EU-The 27 European Union Member States have the European Union Cosmetics Directive The EU Cosmetics Directive (76/768/EEC)
  – Other non-governmental bodies CTFA, CIR, Cosmetic Europe(COLIPA)
Required Process

• Risk assessment of ingredients (Hazard assessment)
  Testings
  – Acute toxicity, Dermal absorption, Dermal irritation, Skin sensitization, mucous membrane irritation.
  – Subchronic toxicity (Skin, Systemic and inhalation toxicity), Phototoxicity
  – Mutagenicity, Teratogenicity, Reprotoxicity

• Product Assessments
  – Depending on the nature of ingredients (incl contaminants evaluation),
  – Exposure (where used and how)

• Action by Authorities
  – Appropriate Labeling (Prop 65, EU Annexes)
  – Outright product recall or ingredient/product Ban
Human Safety Risk Assessment in the Product Development Lifecycle

Throughout the development cycle, risk reduction methods including packaging, labeling and study restrictions may be applied.
Safety Video

- [Link 1](https://www.youtube.com/watch?feature=player_detailpage&v=fvE2VjU9GKM)
- [Link 2](https://www.youtube.com/watch?v=fvE2VjU9GKM&feature=player_detailpage)
The African Scenario

Most assessments and evaluation do not include:

- **Uniqueness of the African continent and the people**
  - Skin color
  - Hair type
  - Habits and Practices (due to culture, social concerns or economic status)

- Rarely can find data, (clinical, invitro, studies, documentation, scientific publications, practices, etc)

- Efforts to change this are starting but very few since it is not mandated so it is very slow
Some African consumer perspectives

Africa-African Consumer are asking for QUALITY Products adapted to their unique needs—but still affordable (http://www.rolandberger.de/media/pdf/Roland_Berger_think_act_study_Inside_Africa_20120327.pdf)

- Skin care products that will adapt and be effective on the skin types and the various diverse shades of skin
- Makeups that will not wash out in the rain or block the pores in under intense sunshine
- Quality products (Soaps, deodorants and body cleansers) that reflects habits and practices—reflecting social and economic realities
- Environmentally compatible and friendly products
Hair difference example


- Hair comparisons (Asian Hair, African Hair and Caucasian)
- Phototrichogram 2 days after shaving
Hair Findings and observation

- **Asian hair** holds the speed record for growth with 1.3 cm a month. On the other hand, it has lower density than any of the other ethnic groups. The way its follicle is implanted causes the hair to grow straight, perpendicular to the scalp

- **African hair**, generally black hair, is the slowest growing of all, at less than 0.9 cm a month. On the other hand it is slightly more dense than Asian hair and grows almost parallel to the scalp, twisting around itself as it grows

- **Caucasian hair** comes between the other two at 1.2 cm a month, but it has the highest density of all. It grows at an oblique angle to the scalp and is slightly curved

- [http://www.rolandberger.de/media/pdf/Roland_Berger_think_act_st udy_Inside_Africa_20120327.pdf](http://www.rolandberger.de/media/pdf/Roland_Berger_think_act_study_Inside_Africa_20120327.pdf)
Aggregate Exposure is important

- Considers ALL sources of exposure to the chemical
  - Products marketed to be used together (within and across product categories)
  - Read labels, READ LABELS!
  - Products used sequentially (wash, condition and fix)
  - Indirect exposures via environmental media
Some Helpful suggestions to Regulators

• We lack data on a lot of essential parameters that will be helpful in assessment (comedogenicity, Habits and Practices data, etc)
• Demand quality (standards are key)
• Eliminate sub-standard and counterfeits products
• Enforce bans (especially if it is banned in other countries)
• Encourage the development of Local expertise (including testing and assessments)
• Lead industrial associations (build partnerships)
• Facilitate education and information sharing
• Accelerate work on harmonization
• Involve consumers
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