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COSMETIC TOILETRY & FRAGRANCE ASSOCIATION OF SOUTH AFRICA

The Cosmetic Toiletry & Fragrance Association of South Africa

Background

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- Debut 1994
- Unanimous agreement, international & local CEO's & CFO's
- Cosmetic Business Sector Trade Association
- Membership categories;

1) **Full Members** – Distributors, Brand owners, Importers and Exporters of finished products.
2) **Manufacturing Members** – Manufacturers, Contract Packers
3) **Associate Members** – Secondary level of cosmetic goods and service delivery. Suppliers of ingredients, raw materials, packaging etc., **not** involved in production, sales and marketing.Associate Membership also includes academic institutions and Laboratories.
4) **Retail Members** – Retail Outlets with their own private label brands and resellers of finished products.

24 years serving the cosmetic industry

CTFA Roles & Responsibilities

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- Collective co-ordinated voice to Government / Media / Stakeholders on behalf of cosmetic industry
- Create a favourable economic and regulatory operating environment, advocating best practice & accountability
- Drive global harmonization of standards via the International Organisation for Standardization (ISO) and the South African Bureau of Standards (SABS)
- Drive harmonisation of African regulatory standards
- Lobbying and participation in international regulatory harmonisation forums
- Support export/import trade opportunities
- Promote Social responsibility (LGFB)

CTFA Roles & Responsibilities

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- Packaging, artwork and label reviews
- Product claims and reports
- Advertising Guidelines – Cosmetic advertising code
- Interpretation and advice on implementation of regulations
- Issue Certificates of Free Sale (exports)
- Assist with Product Information File contents
- Assist with Safety Assessments
- Industry Participation in decision process via Working Groups and Technical Committee (TC)
- Self-monitoring Committee via the CTFA Alternate Dispute Resolution (ADR) status
- Strategic alliances to facilitate imports and exports (DTI / ITAC / CECOSA)

Local regulatory influences

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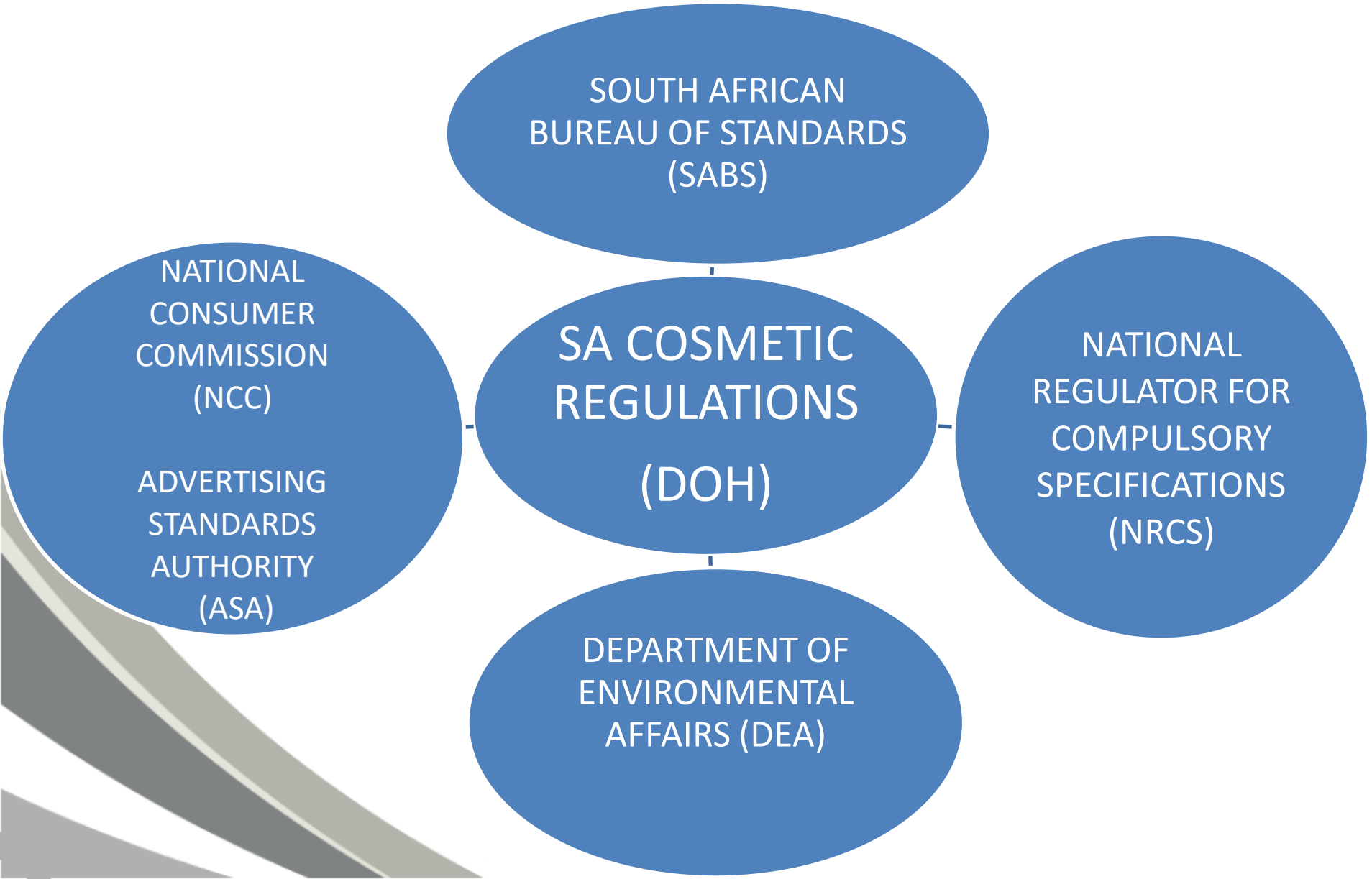

International regulatory influences

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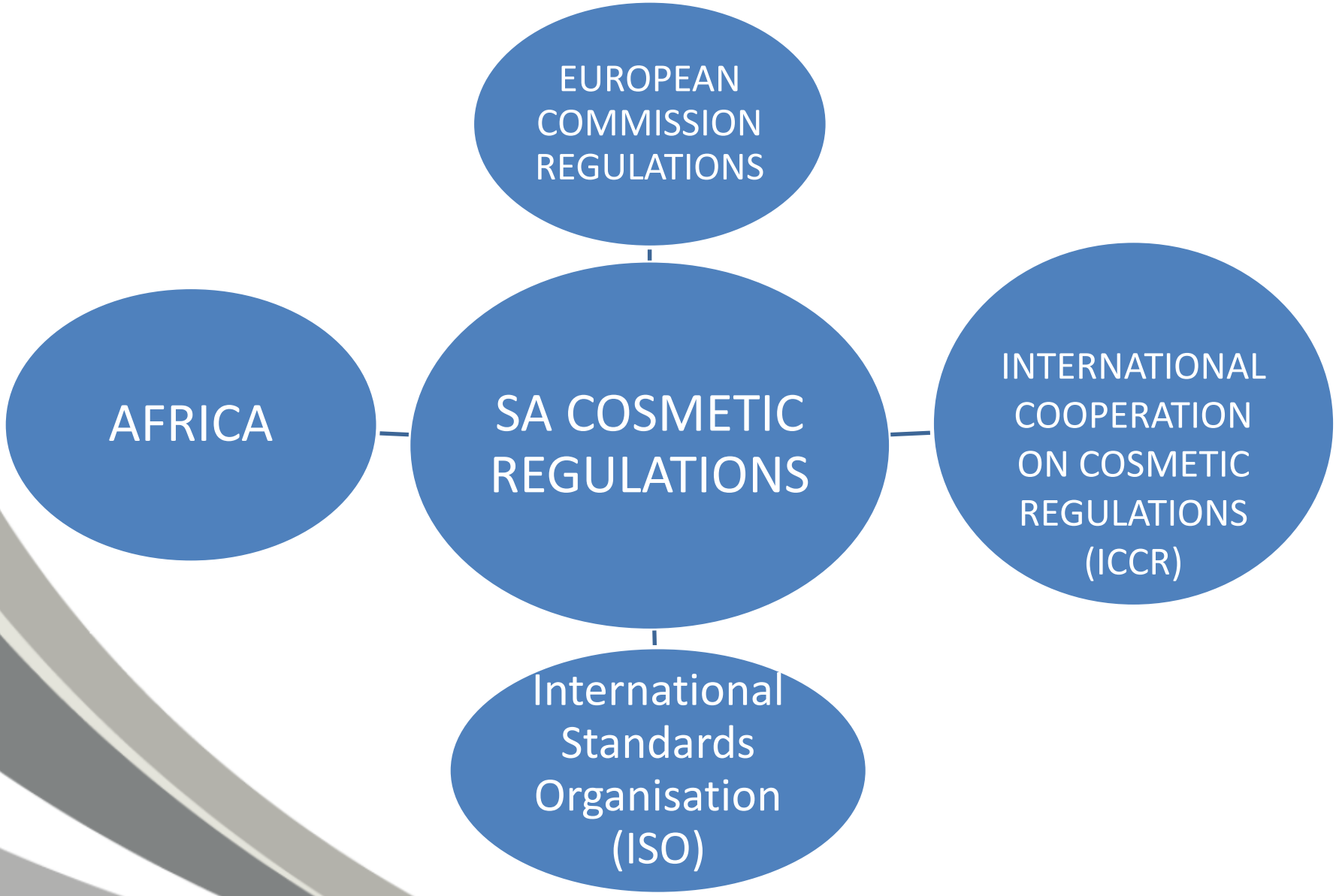

Local and Global Stakeholder Engagement

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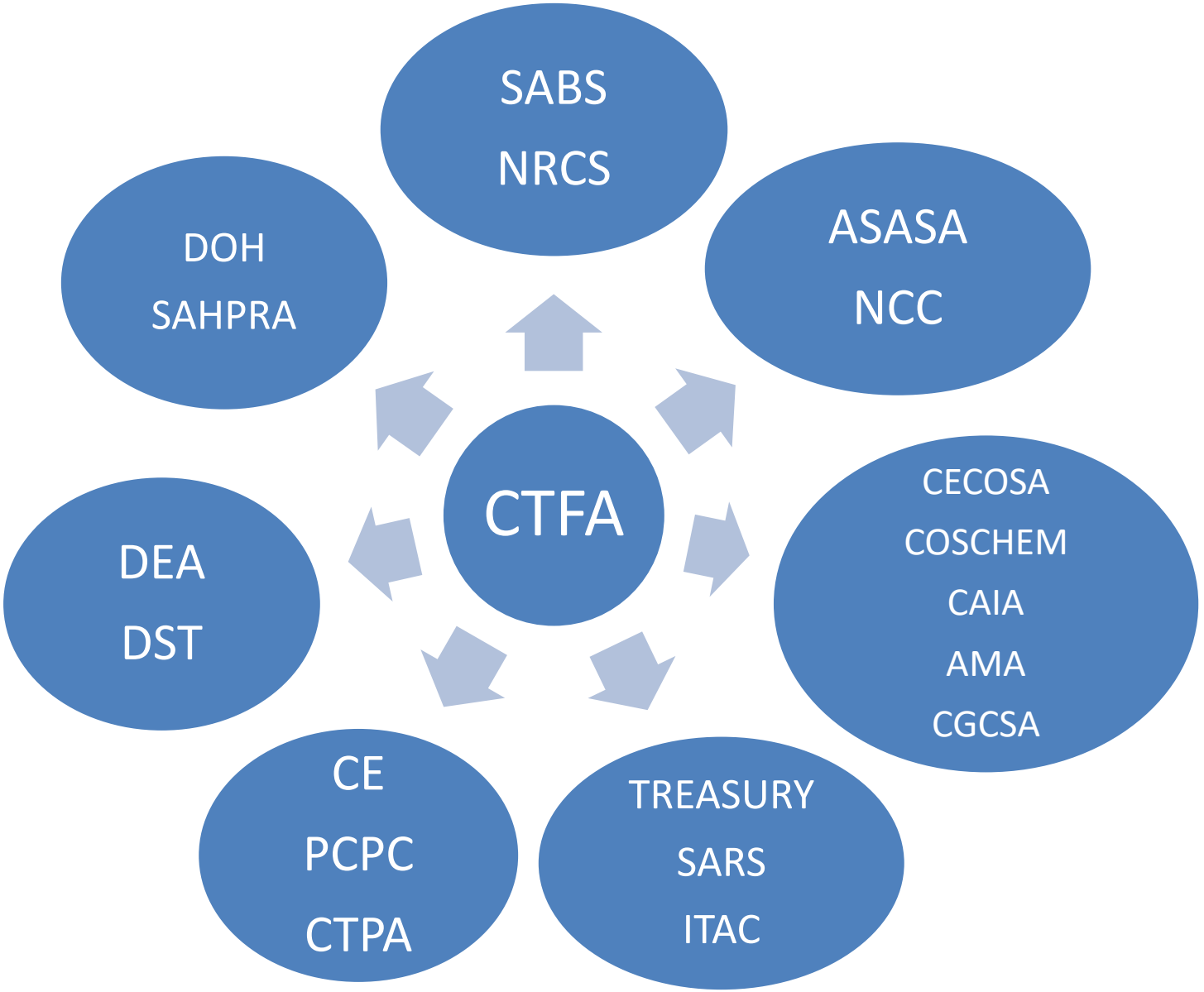

What Regulatory Challenges are focal in 2018?

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- DOH Regulations
- DEA - The National Environmental Management Biodiversity Act (NEMBA) – BABS permits – Amnesty - BioPANZA
- ASA – Advertising code
- Waste Management Plans and Pricing Model
- Animal Protection Bill
- Chemicals Management Plan
- Metrology Bill
- SABS standards / ISO global participation

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MANUFACTURERS - Redraft of Regulations Relating to Labelling, Advertising and Composition of Cosmetics - 22 December 2018 -

June 2018

Dershana Valla
Regulatory Affairs Manager

Content

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Regulatory environment

Draft regulations - 2016

Redraft content – 2017

Responsible person

Redraft: Various articles

Redraft: Industry Impact

Wins and New comments

Conclusion

Regulatory Environment

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- Current environment - Self Regulation
- Impending regulatory environment:
  - DoH – August 2016 Draft Regulations relating to labelling, advertising and marketing of Cosmetic products
  - DoH – December 2017 Redraft - Regulations relating to labelling, advertising and marketing of Cosmetic products
- Industry welcomes regulations as positive step towards furthering product and consumer safety
- Industry committed to continued development of safe, innovative and efficacious products

Draft regulations - 2016

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- CTFA Compendium
- Substantial comments and proposals on Articles and Annexes:
  - Commencement period
  - Transitional period
  - Regulation review
  - Global practice of annual review / update
  - CTFA expert resource sharing
  - Safety – impact on industry
  - In-market control organisation – clarify measures/obligations
  - Product information file – responsibility/making available/retention
  - Product composition – provision for trace substances
  - Labelling – industry impact
  - Annexes – update/align

Responsible person

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- **Definition**: “natural or juristic person(**manufacturer, importer or distributor**) responsible for making the product available on the market”
- Responsible for ensuring **compliance** to the regulations
- Responsible for ensuring that the cosmetic has undergone **safety assessment** of **finished product** and its **ingredients**
- **Contract manufacturer** or **brand owner** or **consultant**

Product manufacture – Value chain

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RESPONSIBLE PERSON

Product development

Product stability testing

Validation: manufacturing process

First manufactured batch

Packing and distribution

- Ingredient TDS / MSDS
- Safety of ingredients

- Safety assessment
- PIF

- Post market surveillance

Redraft - 2017: Content

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Safety : safety assessment

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RESPONSIBLE PERSON

Assessment report:

- Qualitative and quantitative composition
- Physical and chemical/ microbiological characteristics
- Impurities/traces from packaging
- Use of cosmetic
  Exposure to cosmetic
  Exposure to substances
- Toxicological profile of substances
- Undesirable / serious undesirable effects
- Other information
  Assessment conclusion
  Assessors credentials

Trained person

Good Manufacturing Practice

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- Compliance to relevant ISO and SANS standards

- No prescribed standard even though the standards applicable to cosmetic industry is ISO 22716

ISO

SABS
South African Bureau of Standards

Product Information File

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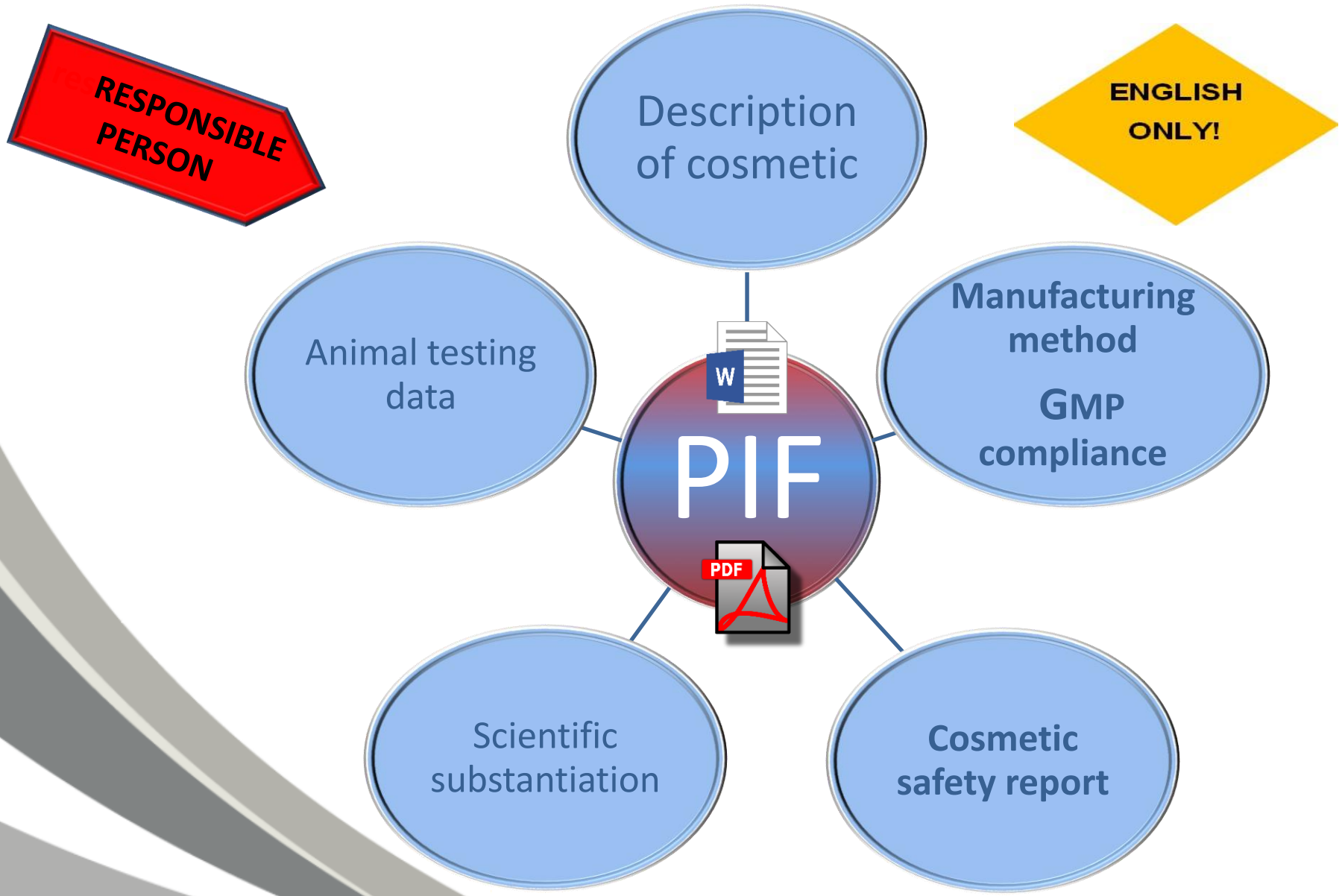

Product Composition

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Annex I	Prohibited substances list
Annex II	Restricted substances
Annex III	List of permitted colourants
Annex IV	List of permitted preservatives
Annex V	List of permitted UV filters

WARNING STATEMENTS

TRACE SUBSTANCES

Labelling

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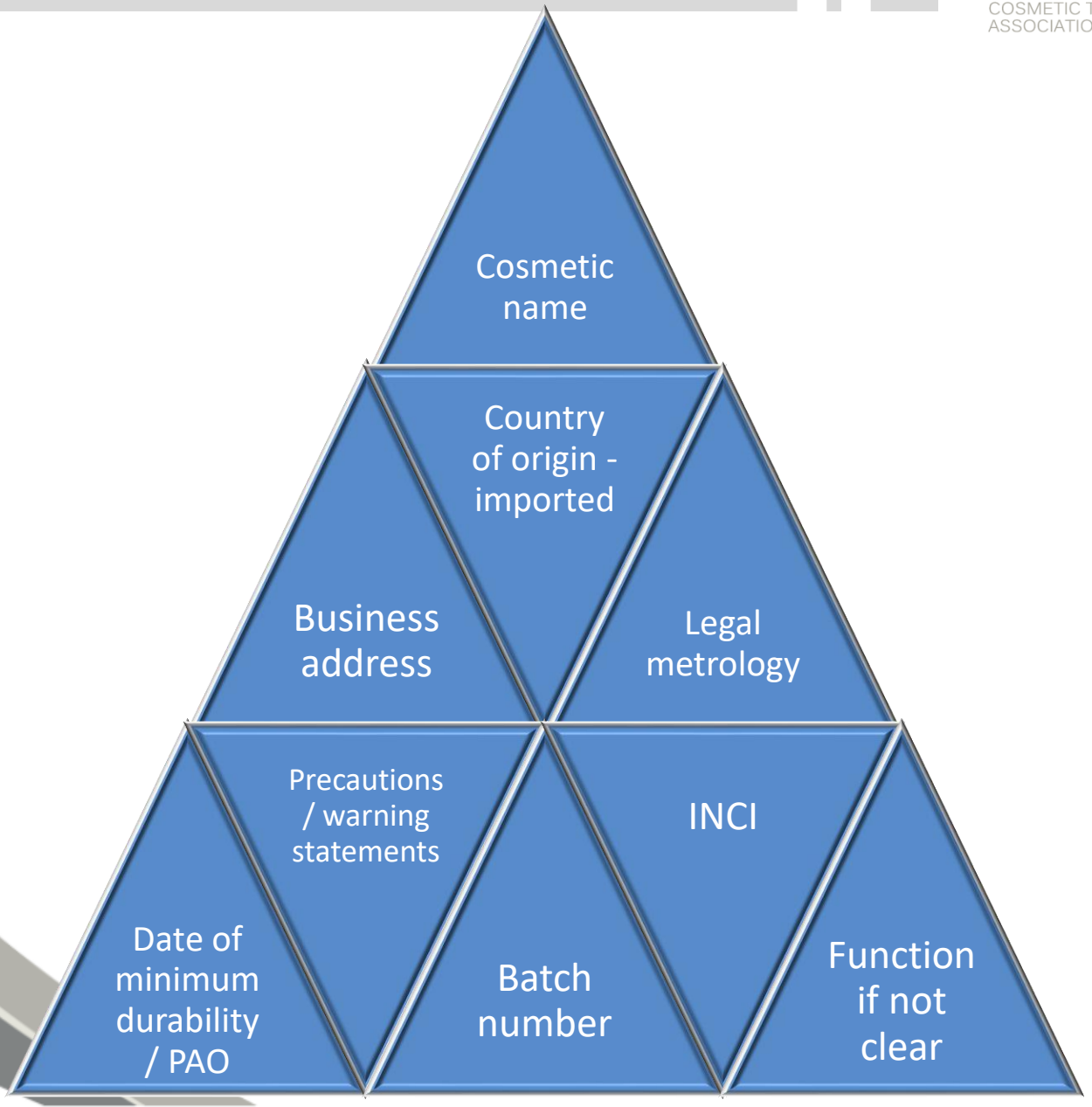

Labelling

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Your Logo Here

Skin Defense

ACNE CLEANSER

8 FL. OZ. (236 ml)

DIRECTIONS:
Apply to face and neck, lather, and rinse with warm water. For best results, use morning and night for daily cleansing.

INGREDIENTS:
Deionized Water, Sodium Laureth Sulfate, Sodium Lauryl Sulfate, Disodium Oleamido-MEA Sulfosuccinate, Cocamide-MEA, Cocamidopropyl Betaine, Glycol Stearate, Melaleuca Alternifolia (Tea Tree) Oil, Salicylic Acid, Hamamelis Virginiana (Witch Hazel) Extract, Hydroxypropyl Guar, Lavandula Angustifolia (Lavender) Oil, Cucumis Sativus (Cucumber) Fruit Extract, Propylene Glycol, Methyl Paraben, Propyl Paraben, Diazolidinyl Urea.

Made in U.S.A.

Distributed by:
YOUR NAME HERE
Any City, U.S.A., Your Zip

Label Size: 4.5" x 2"

Product claims

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- Genuine claims on product function and characteristics
- Claims on nature, effect and quality – scientific substantiation
- “clinically proven” – scientific substantiation
- Claims on medicinal properties – prohibited
- “recommended by doctor” etc. – adequate and appropriate evidence and scientific substantiation
- “skin bleacher” , “ skin lightener” or “ skin whitener” or impression of bleaching , skin lightening or skin whitening – prohibited

Product claims

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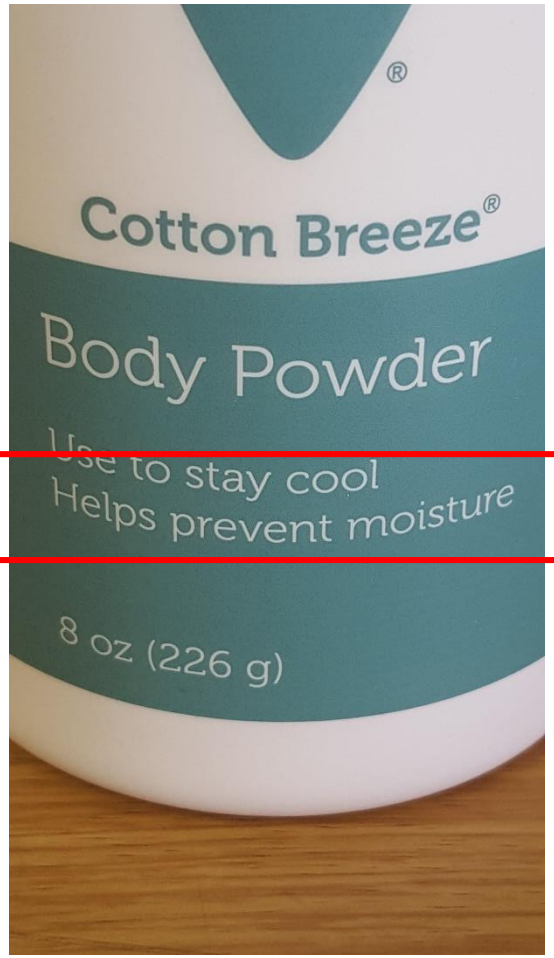

Post-marketing surveillance

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RESPONSIBLE PERSON

CONSUMER REPORTS UNDESIRABLE

OR

SERIOUS UNDESIRABLE EVENT

RECORD IN PIF

CONDUCT REGULAR REVIEWS

DETECT TRENDS AND TAKE ACTION

Redraft: Industry Impact

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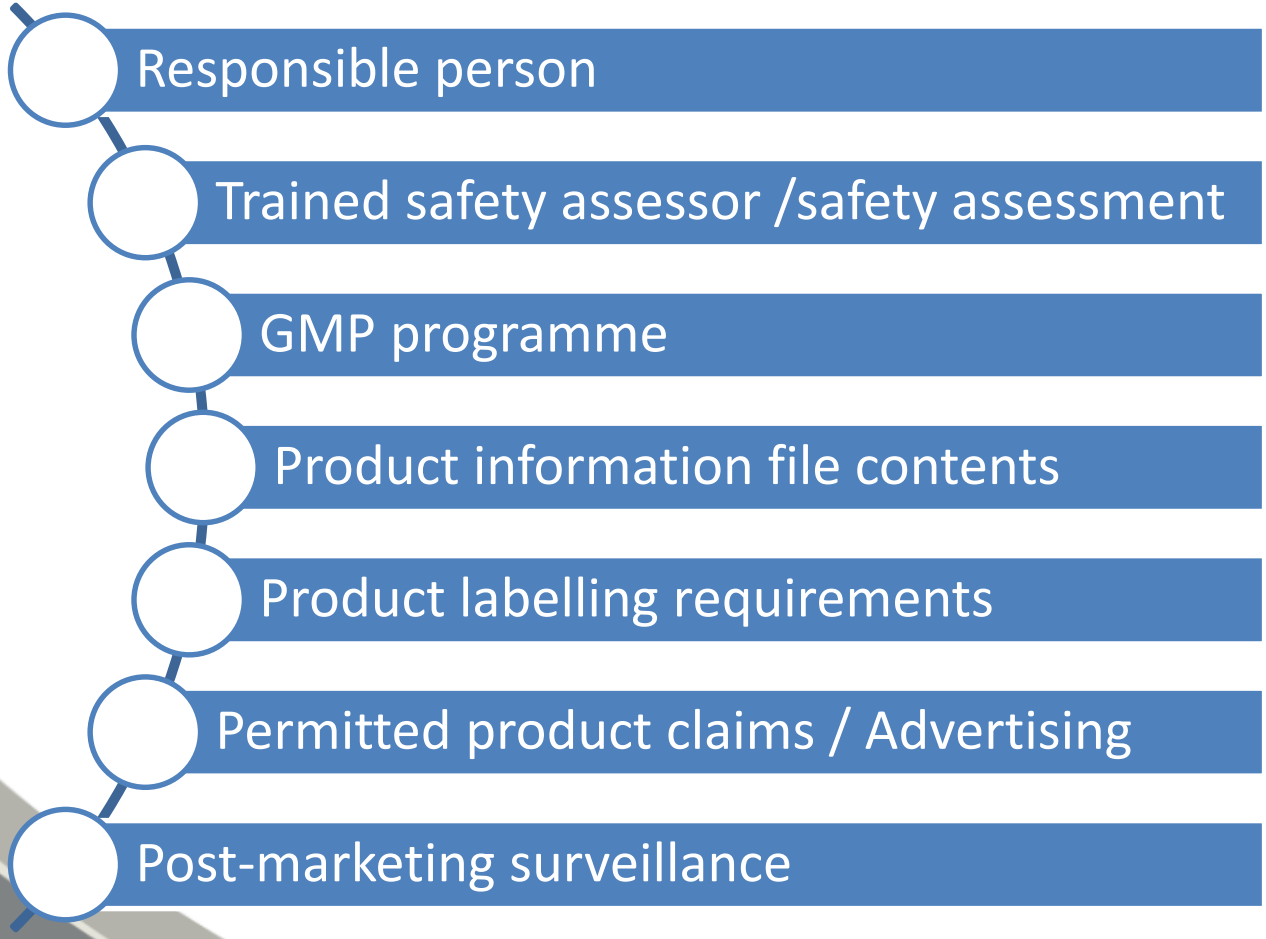
What does this mean for manufacturer's ?



Redraft : Wins vs New comments

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Wins	New Comments
1. Definition: Distributor, nanomaterial, responsible person, scientific substantiation, serious undesirable effect, undesirable effect	**1. Definition:** Cosmetic product, importer, further addition on responsible person, substances
	2. Category of cosmetics: sun protection products, anti-aging products, primary cosmetics with secondary anti-bacterial/anti-fungal function.
3. Responsible person: article included	
4. Safety: safety assessment of product and guideline provided	**4. Safety:** Timeframe for compliance – 2 years
5. Good manufacturing practice: Not prescriptive on GMP standard and certification. ISO and SANS recognised	**5. Good manufacturing practice:** Also recognise any other internationally recognised standards for GMP.

Redraft : Wins vs New comments

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Wins	New Comments
6. Product Information File: • 10 years retention from last batch manufacture • Allocate responsibility to responsible person	**6. Product information file:** • 3-5 day period to make PIF available
7. Product composition: • Annexes mostly updated as proposed • Trace substances permitted	**7. Product composition:** • Numbering of Annexes need to aligned to Regulation EC 1223/2009 • Provision should be made to recognise use of ingredients outside the functions designated in Annexes and without max limits and warning statement. eg. Benzyl alcohol

Redraft : Wins vs New comments

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Wins	New Comments
8.Labelling: • Align with SANS98 • Align with Legal metrology requirements • Address requirements adopted • Date of min. durability not applicable for products with >30 months durability • Trace of prohibited substances addressed as allowed	**8.Labelling:** • Allow BB or expiry date or best before instead • Transition period for date of minimum durability compliance • Transition period for use of PAO symbols on label • Should not be prescriptive on where animal testing information should appear as some products do not have secondary container
9. Prohibited claims: • Cannot allow implied claims on product function or characteristics which are not true • Medical professional endorsement allowed if scientific substantiation is adequate and appropriate	**9. Prohibited claims:** • Unless claims have substantiation they are prohibited • All claims require substantiation

Redraft : Wins vs New comments

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Wins	New Comments
10.Post-marketing surveillance: Adopted proposal to include: • responsibility, • record and review of desirable and serious undesirable events	**10. Post-marketing surveillance:** Important to distinguish between the type of information to be recorded for undesirable and serious undesirable events

Conclusion

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- Comments submission 22 March 2018 - representative of cosmetic industry concerns

- Proposals based on
  - 20 years experience as self-regulated industry
  - Expert opinion on local and international cosmetic industry best practice

- Post commentary period:
  - Continued CTFA / DoH engagement/negotiation
  - Public workshop by DoH
  - Promulgation by DoH
  - Ongoing Guidelines and updates
  - CTFA advisory role to regulator and members

Thank you
The CTFA invites you to take advantage of our services as you prepare for your regulatory journey.

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"Setting & Maintaining World Class Standards, Principles & Practices in our Industry."