



Welcom e











2018 – 2019 At A Glance Breakfast | Programme

Thursday 8th November 2018, Hurlingham Office Park

Book Here

09.00-09.30 Light Breakfast & Refreshments

09.30-10.15
Welcome: Mrs Adelia Pimentel: CTFA Director
2018 9ta glance: CTFA Team

10.15-10.45
A focus on Manufacturing & Exports
Ms Sinah Mosehla: Director-Cosmetics Desk at the Department of Trade & Industry (DII)

10.45 11.00 Regulatory Outlook for 2019: CTFA Team

> 11.00-11.30 Networking & Refreshments: All

> > 11.30 Close

""Come and Join us at our new premises: Huningham unice Hart, Block B, Ground Hoor, 19 Woodlands Avenue, Husingham, Sandron

P. D.Bur 725, Bendyark Rüge, 1550 Tel. +27 to 795 4271 Fax: +27 to 794 3030 Evrall, 11/2/Life Code

BULLI PRULIFICATIV. ROSSI(charpenon) u entonae i movitor, A Bala, A Presstal Describe Director C. Piller, I. Cullot, W. Van Wyk



The CTFA Team



Adelia Pimentel Executive Director



Anina van der Walt Head: Regulatory Affairs & Policy Analysis



Dershana Valla Regulatory Affairs Manager



Omphile Lehau Membership & Development Officer



Samantha Lotkin Receptionist & Office Administrator



Annique Detter Accountant



20 years experience in Pharmaceutical, cosmetics and food focused companies

BSC Honours - Microbiology from University of the Witwatersrand Cosmetic Science Diploma Bachelor of Arts (Psychology) University of the Witwatersrand

CTFA June 2016

Technical Portfolio Regulatory Affairs Manager

- Member Enquiries SMEs
- DOH
- NRCS
- Cosmetic Code
- ICCR
- TC
- Adhoc Workgroups: Haircare



Technical Portfolio Head: Regulatory Affairs & Policy Analysis

17 years experience in the pharmaceutical and cosmetic industry. Anina is a registered pharmacist since 2001.

B.Pharm (Pharmacy at NWU)
M.Sc Pharmaceutics (cum laude)
specialising in cosmetic product
design (NWU, Potchefstroom,
South Africa).
Safety Assessment of Cosmetics
in the EU (VUB, Belgium).
Bioengineering skin
measurement device advanced
training (Courage & Khazaka,
Germany).

- Member enquiries multinationals & Retailers
- SABS
- ISO
- WTO
- DEA Biodiversity
 - IWMP
- DST
- Adhoc Workgroups: Suncare





South African

Cosmetic Regulatory Environment

'2018 At a Glance'





Adelia Pimentel Executive Director



Local regulatory



OUTH AFRICAN BUREAU OF STANDARDS (SABS)



SA COSMETIC REGULATION S

(DOH)

DEPARTMENT OF ENVIRONMENTAL AFFAIRS (DEA)



NATIONAL
REGULATOR
FOR
COMPULSORY
SPECIFICATIONS
(NRCS)

International regulatory influences



EUROPEAN COMMISSION REGULATIONS

AFRICA

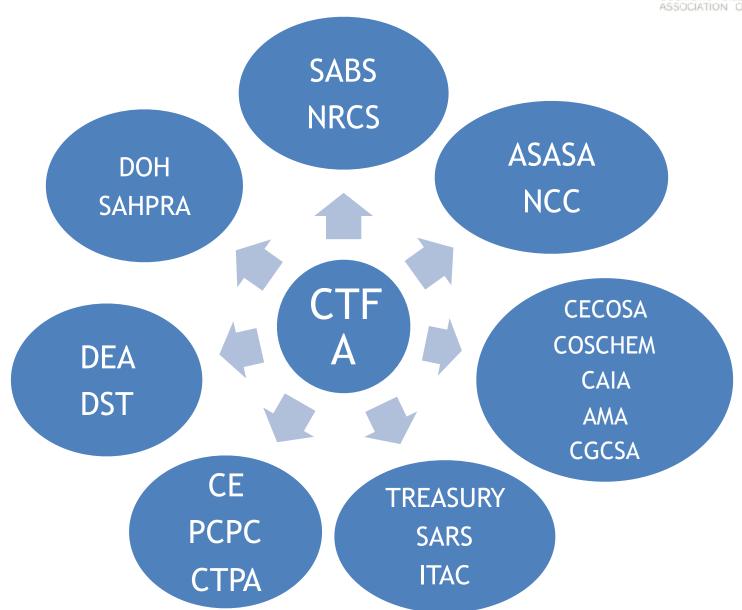
SA COSMETIC REGULATIONS

INTERNATIONAL COOPERATION ON COSMETIC REGULATIONS (ICCR)

International
Standards
Organisation
(ISO)

Local and Global Stakeholder Engagement





SA Landscape



- South African challenges
 - Political
 - Social
 - Economical
- Cosmetic industry in South Africa
 - 0.1% of GDP
 - Employment numbers in cosmetic industry = 60 000 (2015)
 - Total size of beauty industry in S.A. = R25.3 billion (2015) (includes Cosmetics, aerosols, roll-ons and personal care)
 - % of SMEs in industry = 80% (based on CTFA membership)
- Government mandate/focus
 - Grow local economy
 - Support local business development (SMEs)

An **SME** in **South Africa** is any enterprise with fewer than 200 employees and/or an annual turnover of less than R64 million. A micro Enterprise will have an annual turnover of less than R1million



Department of Health (DOH)

- DoH Redraft commentary March 2018
- Roadshows to create awareness (Johannesburg, Durban, Cape Town)
- Debriefing sessions for:
 - Manufacturers
 - Brand Owners/Distributors
 - Raw Material Suppliers
- Letter to DOH proposing cosmetic structure within DoH















Dershana Valla Regulatory Affairs Manager



Regulatory Environment



- Current environment Self Regulation
- Cosmetics are governed by the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1954 (Act 54 of 1972) together with the supporting regulations
- The last amendment to the Act, relating to cosmetics, was published in February 2008, where the definition of a cosmetic was amended
- Regulations relating to the labelling and advertising of Foodstuffs, Cosmetics and Disinfectants were first published in May 1977 with the last amendment in November 1985
- The regulations were lacking in depth in relation to the sale and control of Cosmetics and required extensive review

Redraft - 2017: Articles



Definitions

Category of cosmetics

Penalties
Short title
Commencemen
t

REGULATION

Amendment to Annexes Repeal

> Postmarketing surveillance

Responsible person
Safety
GMP
PIF

Product composition
Labelling
Product claims
Advertising

Are you ready?



Manufacturer's, Distributors, Raw ingredient manufacturers and suppliers

ave you identified a Responsible person?
you have a Trained safety assessor ?
ave you implemented a GMP programme
ave you started to put a Product information file gether?
you meet the Product labelling requirements?

e your Product claims / Advertising permitted?

have a Post-marketing surveillance process in place?



Positive changes	Future expectations
1. Definition: Distributor, nanomaterial, responsible person, scientific substantiation, serious undesirable effect, undesirable effect	1. Definition: Cosmetic product, importer, further addition on responsible person, substances
3. Responsible person: article included	
4. Safety: safety assessment of product included and guideline provided	4. Safety: Timeframe for compliance - 2 years



Positive Changes	Future expectations
5. Product Information File:	5. Product information file:
 10 years retention from last batch manufacture Allocate responsibility to responsible person 	3-5 day period to make PIF available
6. Product composition:	6. Product composition:
 Annexes updated as proposed Trace substances permitted 	 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.



Positive Changes	Future expectations
8.Labelling:Align with SANS98Align with Legal metrology	8.Labelling:Allow BB or expiry date or best before instead
 Address requirements adopted Date of min. durability not applicable for products with >30 months durability Trace of prohibited substances addressed as allowed 	 Transition period for date of minimum durability compliance Transition period for use of PAO symbols
9. Prohibited claims:	9. Prohibited claims:
 Disallow implied claims on product function or characteristics which are not true Medical professional endorsement allowed if scientific substantiation is 	Unless claims have substantiation they are prohibitedAll claims require substantiation



	ASSOCIATION OF SOUTH AFRICA
Positive Changes	Future expectations
10.Post-marketing surveillance:	10. Post-marketing surveillance:
• responsibility,	Important to distinguish between the type of information to be recorded for undesirable and serious undesirable events

What are the next steps?



Continued CTFA / DoH engagement/negotiation

Public workshop

Promulgation

Guidelines and updates

CTFA advisory role



South African Bureau of Standards (SABS)

- Participants on work groups at national level
- SANS local standards development
 - SABS TC217 Suncare Analytical Methods Microbiology
 - SANS1557 (Suncare) published for comments in 2018
 - Natural and organic standards published in 2018
 - SABS TC229 Nanotechnology involvement
 - SABS TC070 Legal metrology legal metrology act was published late 2018
 - Toothpaste standard (Kenya)

National Regulator for Compulsory Specifications (NRCS)

 SABS TC070 Legal metrology – legal metrology act was published late 2018 (SANS 289)



Department of Environmental Affairs (DEA)

- Biodiversity Forum participation South Africa signed the Nagoya Protocol (2013), as part of efforts to protect indigenous fauna and flaura
 - National Environmental Management: Biodiversity Act (NEMBA)
 - IKS Bill Department of Science and Technology
- Waste Management Plans Section 28
- Multi-Stakeholder Committee for Chemicals Management (MCCM)

MINAMATA Convention on Mercury – aimed to reduce mercury anthropogenic emissions and releases in various industries.

The international treaty has been signed by 128 UN member states and ratified by 74 countries, which are now legally obliged to comply with its provisions.

Microbeads in Cosmetics – Presentation on 21November - Global drive



Department of Trade & Industry (DTI)

- ❖ Technical Barriers to Trade (TBT) Forum participation
- Certificates of Free Sale endorsement
- GMP Training for SMEs (Incubators)

Further Industry Drives

- Advertising Standards Authority of South Africa (ASASA)
 - Member of Interim Board
 - Cosmetic code annual update
 - Advertising Regulatory Board (ARB) 5 November 2018
- Animal testing ban proposal attested DAFF contacted and support gained
- MEDIKREDIT contacted after a complaint was received that nappi codes were being allocated cosmetics



Further Industry Drives

- Legal advice sought on SAHPRA formation and how this will affect the cosmetic industry
- Lobbying with new CANSA representative
- CHIETA Member of Skills Forum Feb 2018
- JCCI endorsement of Certificates of Free Sale renewed
- Suncare seminar SANS1557 training
- Biodiversity session April 2018
- Ad Valorem session March 2018
- French Embassy presentation imports/exports SA
- Presentation at Africa Home & Personal Care conference September 2018





- International Cooperation on Cosmetics Regulation (ICCR) representation with SA Regulator - update on regulatory status from industry perspective – June 2018 – Japan
- International Organisation for Standardization (ISO) May 2018 in Poland and November 2018 – Monaco
- Brazil INCl description translation to Portuguese ABIHPEC (industry association in Brazil) – support to remain unchanged
- Personal Care Products Council (PCPC)
- Cosmetics Europe (CE)
- European Personal Care Association (CTPA)
- Sub-Saharan Africa Task Force (SSA) engagement on pertinent matters throughout the year
- Manufacturers Association of Nigeria (MAN)





"Setting & Maintaining World Class Stc Principles & Practices in our Indust





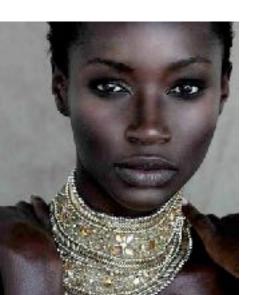






CTFA Regulatory Outlook for 2019





CTFA Team



CTFA 2018 - 2023



Long-Term Strategy 2018 – 2023

- To be known as the Regulatory Experts and undisputed voice of the cosmetic industry in South Africa both locally and globally.
- Continuously advocate 'protection of consumers' through a compliant and ethical industry

How we will get there:

- **2018 2019** Refine the CTFA foundation, internal processes and lobbying capacity
- 2019 2020 Procure pro-active partnerships with synergistic stakeholders (both government and private) with a view to enhancing member benefits
- **2020 2023** Develop internal and external expertise base and continuously reassess strategic focus locally and internationally



CTFA trainings, TC meetings & proposed dates for 2019

TC dates

CTFA training & workshops

Other...next slide

24 January, 14 March, 15 May, 18 July, 26 September & 27 November

Cosmetic GMP training (2019 week 7, Feb)

Responsible person (RP) training (week 15, April)

Label claims, clinical trials and product assessments (week 33, Aug) Haircare standard (week 42, Oct)





Regulatory training as per member requirements

Relevant regulatory changes or challenges

Current cosmetic regulations

Strengthening your regulatory team

SANS & ISO standard s training

Cosmetic product Safety Assessments

7

?



Summary:

- Procure pro-active partnerships/MOUs with synergistic stakeholders with a view to enhancing member benefits
- Create awareness of the CTFA proposition at various forums
- Focus on training to ensure industry compliance
- Focus on members' needs and tailor-make benefits:
 - Brand Owners
 - Manufacturers
 - Raw Material suppliers
 - Retailers
 - Academia
- Focus on Africa Harmonisation Technical Barriers to Trade
- Global Regulatory Summit "Africa and the World" October 2019





Thank you



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