



CosmetSA (Pty) Ltd

COSMETICS REGULATORY SOLUTIONS

“Cosmetics compliance –
can we decipher
regulations through a
global lens?”

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PRESENTATION CONTENT

- ❖ Brief regulatory overview and background
- ❖ EU Regulations vs SA draft Regulations
- ❖ Challenges
- ❖ Global cosmetics regulatory trends & Conclusion



OVERVIEW AND BACKGROUND

Disclaimer

SA legislation status (current)

- ❖ Currently self-regulatory
- ❖ Industry best practices and guidance documents
- ❖ Draft regulations published for industry comment Aug 2016 and Dec 2017
- ❖ R. 1469, Foodstuffs, Cosmetics and Disinfectants Act (54/1972): Regulations relating to the labelling, advertising and composition of cosmetics (draft)



OVERVIEW AND BACKGROUND

EU legislation status

- ❖ Economic and political union of 28 (?) member states
- ❖ Ensure free movement of people, goods, services, and capital **key legislation was required to be harmonised**
- ❖ In areas of EU harmonised legislation, local enforcement authorities appointed
- ❖ Each Member State decide which ministry is the competent authority for a given legislation
- ❖ 1976 – 2013: EU Cosmetics Directive required Member States to implement the EU text into own laws
- ❖ **EU Regulation (EC) 1223/2009** of the European parliament and of the council of 30 November 2009, on cosmetic products replaced the **Directive 76/768/EC**



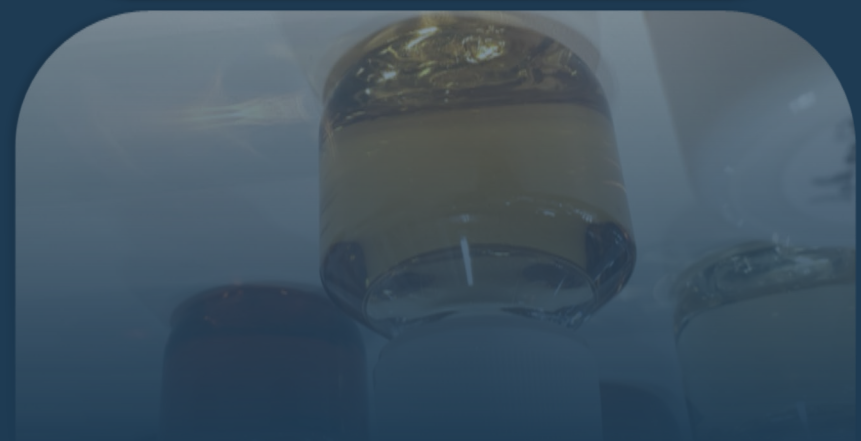
OVERVIEW AND BACKGROUND

...EU legislation status

EU Regulation - in force since 11 July 2013

EU Regulation basic principles

- ❖ In-market control
- ❖ No pre-market registration/certification
- ❖ Product notification prior to placing on the market (CPNP)
- ❖ Responsibility for safety and legal compliance is with the RP (EU RP)
- ❖ Control of compliance by authorities



OVERVIEW AND BACKGROUND

US legislation status (current)

- ❖ Currently voluntary “registration”
- ❖ Regulatory structure originally established in 1938
- ❖ Cosmetics =
US Food and Drug Administration (FDA)
- ❖ FDA has limited authority
- ❖ Introduction of the Personal Care Products Safety Act = U.S. FDA may soon be able regulate CP and PCP's



OVERVIEW AND BACKGROUND

...US legislation status (current)

Proposed Personal Care Products Safety Act
provide for FDA to have authority to:

- ❖ Recall PCP's (consumer safety)
- ❖ Labelling requirements
- ❖ Require complete label information - posted online
- ❖ Companies to provide contact information and report SAE to the FDA within 15 days
- ❖ Annual registration for manufacturers and provide information on the ingredients used
- ❖ Good Manufacturing Practices regulations for PCP's
- ❖ Funding of oversight activities
- ❖ Collect user fees from personal care product manufacturers.



EU vs SA LEGISLATION (draft)

EU: Regulation EC No 1223/2009	SA: R. 1469, FCD Act (54/1972): Regulations relating to the labelling, advertising and composition of cosmetics (draft Dec 2017)
Scope, definitions (Art 1-2)	Definitions, Category of Cosmetics (Art 1-2)
Safety, RP, Obligations RP & Distributor (Art 3-7)	RP (Art 3)
GMP (Art 8)	GMP (Art 5)
Free Movement (Art 9)	
Safety Assessment (Art 10)	Safety (Art 4)
PIF (Art 11)	PIF (Art 6)
Notification (Art 13)	
Restrictions for substances, CMR, Nanomaterials & Prohibited substances (Art 14, 15, 16, 17)	Product Composition (Art 7)
Animal Testing (Art 18)	
Consumer Information: Labelling (Art 19)	Labelling (Art 8)
Consumer Information: Product Claims (Art 20)	Product Claims (Art 9)
	Advertising (Art 11)

EU vs SA LEGISLATION (draft)

EU: Regulation EC No 1223/2009	SA: R. 1469, FCD Act (54/1972): Regulations relating to the labelling, advertising and composition of cosmetics (draft Dec 2017)
Market Surveillance: In-market control (Art 22)	
Market Surveillance: Communication of SUE (Art 23)	Post Marketing Surveillance (Art 10)
Market Surveillance: Information on substances (Art 24)	
Non-compliance, safeguard clause: Non-compliance by RP (Art 25)	Penalties (Art 12)
Non-compliance, safeguard clause: Non-compliance by Distributors (Art 26)	
Non-compliance, Safeguard Clause (Art 27)	
Non-compliance, safeguard clause: Good Administrative Practices (Art 28)	
Administrative cooperation: Cooperation between authorities, etc. (Art 29-30)	
Implementing measures, final provisions: Amendment of annexes, Repeal, Procedures, etc. (Art 31-40)	Repeal (Art 13)

EU vs SA LEGISLATION (draft)

EU: Regulation EC No 1223/2009	SA: R. 1469, FCD Act (54/1972): Regulations relating to the labelling, advertising and composition of cosmetics (draft Dec 2017)
ANNEX I: CPSR	
ANNEX II: List of substances prohibited in CP's	ANNEX I: List of substances which must not form part of the composition of cosmetics
ANNEX III: List of substances which CP's must not contain except subject to the restrictions laid down	ANNEX II: List of substances which cosmetics must not contain, except subject to restrictions laid down
ANNEX IV: List of colorants allowed in CP's	ANNEX III: List of colouring agents allowed for use in cosmetics
ANNEX V: List of preservatives allowed in CP's	ANNEX IV: List of preservatives allowed in cosmetics
ANNEX VI: List of UV filters allowed in CP's	ANNEX V: List of UV filters allowed in cosmetics
ANNEX VII: Symbols used on packaging/container	ANNEX VI: Symbols used on packaging/container
ANNEX VIII: List of validated alternative methods to animal testing	
ANNEX IX: Part A, Repealed Directives with its successive amendments	
ANNEX X: Correlation table (Directive 76/768/EEC vs Regulation EC No 1223/2009)	



CHALLENGES

- ❖ CP and PCP lifecycle - timeframe
- ❖ Annex info updates
- ❖ CMR
- ❖ Endocrine disruptors
- ❖ UV filters
- ❖ Nanotechnology
- ❖ Safety assessments final products - substance exposure and toxicological profile
- ❖ GMP

CONCLUSION

Global convergence is this possible?

WTO TBT - Regulatory TREND indicator

View the Cosmetic draft regulations specifying the production, operation, labelling and advertising, legal responsibilities and other content published for industry comment, by:

- ❖ Korea
- ❖ USA
- ❖ Argentina
- ❖ China
- ❖ Plurinational State Of Bolivia, Colombia, Ecuador, Peru
- ❖ The Separate Customs Territory Of Taiwan, Penghu, Kinmen And Matsu
- ❖ United Arab Emirates
- ❖ Kingdom Of Bahrain, State Of Kuwait, Oman, Qatar, Kingdom Of Saudi Arabia,
- ❖ Yemen
- ❖ Brazil
- ❖ Israel, etc...



THANK YOU

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