ctfa
COSMETIC TOILETRY & FRAGRANCE ASSOCIATION OF SOUTH AFRICA

20 March 2018

SAHPRA - The Acting CEO
The National Department of Health
Private Bag X828
Pretoria
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Attention: Ms Portia Nkambule

The Cosmetic, Toiletry and Fragrance Association (CTFA) represents 80% of cosmetic companies in South Africa. These range from small to medium enterprise local companies up to and including major multi-national cosmetic companies. The CTFA is grateful for the continuous engagement and opportunities for face-to-face presentations of the industry's concerns and challenges, post the commentary period in November 2016. We are pleased with the changes that have been adopted and the concerns that have been acknowledged, as a result.

The cosmetic industry has developed comments to the proposed re-draft of the Regulations relating to advertising, labelling and composition of cosmetics, published by the Department of Health, on the 22nd of December 2017, in Government Notice R1469.

The membership of the CTFA welcomes the proposal of these regulations as a positive step towards international compatibility of the local regulatory system for cosmetics as well as being a proponent of elevated considerations for consumer safety. Furthermore, the membership of the CTFA is committed to the continued development of safe, innovative and efficacious products as it has been in the past 20 years where CTFA has overseen the self-regulatory system for cosmetics. The comments included in this submission highlight areas that require alignment with international and local best practice as well as practical challenges and impacts that the industry will experience with the current proposed regulations. Our aim is to enhance an industry that has thrived under self-regulation and thus request additional time for compliance of certain aspects, for critical players in our industry, following the promulgation of this regulation.

Herewith are the moderated and consolidated comments as submitted by CTFA Member companies.

GENERAL COMMENTS AND INTRODUCTION

The specified commencement procedures provided in the proposed regulation is not realistic as a compliance period is not included. It is important for the cosmetic industry to understand the timelines it will be afforded to comply with the regulation. We request that various compliance periods be considered in-line with the various levels of intricacy that will be introduced by some of the requirements in the regulation.

We propose that the Industry be given a transitional period for compliance as was the case in Europe when the EU moved from the Cosmetic Directive to the new cosmetic regulation that came into effect in July 2013. We propose to the regulator to allow an implementation period of at least 2-3 years in order to ensure business continuity, especially for the small and medium sized companies.

We anticipate that the timelines envisioned by the regulator in line with the legislative process, will include a process where the cosmetic industry will be afforded an audience to explain and workshop

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with the regulator on these submitted comments through stakeholder consultation meetings. At these meetings, we anticipate that comments will be reviewed by the regulator together with cosmetic industry stakeholders. It is further envisioned by the cosmetic industry that a key part of this process will include a socio-economic impact assessment.

Whilst it is accepted and acknowledged that the articles included in the proposed regulation are necessary, such regulations should be ever evolving and kept up to date. We urge the Department to include a provision in the draft regulation, to provide that the regulation in its entirety, will be annually reviewed in consultation with a trade association(s) which has proved to the satisfaction of the Authority that it is representative of cosmetic persons in South Africa and that collectively possesses the necessary cosmetic expertise. Given that there is legal precedent for relying on trade associations in the Electronic Communications Act, 2005, it is submitted that the inclusion of the aforementioned provision would not only ensure fast-tracking of the review process of the regulations so that the regulation remains up to date and current, but would also afford the Department the opportunity to benefit from the collective expertise on matters specific to the South African cosmetic industry as well as effective resource management. These will be provided by the cosmetic industry through the CTFA as its representative trade association.

SPECIFIC COMMENTS ON THE PROPOSED DRAFT REGULATION

Definitions

We propose the clarification and expansion of the scope with the addition of currently proposed definitions. The further definitions are intended for inclusion in the proposed draft regulation. Based on current local industry practice, we believe that the inclusion of these definitions will assist in supporting the intention of the proposed draft regulation, provide more clarity as well as introduce local and global practices that will make the proposed regulation more robust.

These definitions include but are not limited to **cosmetic product (as defined in the Act & EU), responsible person (additional clarification), distributor, colourant, importer, substances.**

Category of cosmetics

We propose the addition of certain categories that are currently recognised as cosmetic products.

Safety

There is a requirement on the regulator's part to be reasonable in the enforcement of these provisions and the granting of a transition period for compliance, for the cosmetic industry to adapt to the regulatory shift from self-regulation to formal regulation on this matter.

A further request is made of the regulator on this topic, i.e. that it be made clear in the regulation that safety assessments conducted internationally and the safety assessors that conduct them will be acceptable to it. In addition, the requirement for, "an appropriately trained person" to conduct safety assessments must be better explained, through a guideline issued by the regulator.

Good manufacturing Practice (GMP)

We welcome GMP compliance as proposed in the re-draft of the regulations and in accordance with SANS/ISO, however since we are an essential part of the global trade village, products manufactured

in other countries and imported into the local market, it is essential that the other internationally accredited GMP standards, also be recognised by the regulator.

Product Information File (PIF)

We welcome the definition and responsibility of the responsible person with regards to the PIF. We believe that it is prudent to mention in article (6) the period within which the file must be presented to the regulator upon request, we thus propose specifying a period within which the Product information file must be submitted following request from an inspector.

Product Composition

We welcome the provision of the existence of trace substances in the redraft of the regulation. However, we are deeply concerned about the misalignment of the Annex numbering in the current redraft of the Regulations. In the self-regulated environment, the CTFA provided the Cosmetic Compendium as a guideline for Industry. This document was aligned with the Regulation EC 1223/2009 with regards to the Annexes. This enabled the ease of the regular review, reference and update of the information in the Annexes.

Labelling

Some of the provisions in this section of the proposed draft regulation have previously not been part of the self-regulatory system and thus current cosmetic industry practice. These are in respect to the information appearing on secondary & primary packaging, multiple address, ingredient listing, date of minimum durability, application of the PAO symbol and harmonized aerosol labelling practices. The cosmetic industry is not opposed to these provisions, as a result we had proposed workable solutions to them in our submission. It is imperative that a transition period for compliance is considered to afford member companies enough time to change and adapt to the new regulatory requirements when the proposed draft regulation comes into force. The proposals are included in the detailed comments of this submission.

Product Claims

The requirement for scientific substantiation has been a mandatory requirement for claims made irrespective of the type of claim made. This ensures responsible marketing and compliance to specific scientific methods to ensure consumer safety. It is therefore a concern that the redraft proposes the necessity for scientific substantiation only for a specific group of claims. This may lead to confusion and result in divergence from current best practice, with possible misinformation to the consumer.

Post-marketing surveillance

We welcome the article in the proposed regulations, however, in order to ensure that the record keeping and investigation processes are optimized for the purpose of trending and subsequent actioning, it is imperative to distinguish between the type of information that is required, depending on the type of the adverse event.

Procedure for the Amendment of Annexes and the Regulation in general

The cosmetic industry proposes that on the basis of available, credible scientific safety data, the regulator considers motivation for the amendment of the articles of the regulatory text and Annexes I-VI on an annual basis from the cosmetic industry. Submissions shall be made for consideration by

the Department of Health for inclusion into the articles and the Annexes of the proposed draft regulation.

Annexes

The Annexes in the redraft of the regulation as proposed have some editorial omissions and require update in some cases. The detailed part of this submission includes the corrections and updates based on the most recent information available in the Regulations EC 1223/2009 and recent EU Directive, with specific consideration of some unique nuances specific to the South African Cosmetic Industry. The annexes are driven by consumer safety and available safety data, it is therefore important to ensure that they are current to ensure that the cosmetic industry acts responsibly to continue to provide safe cosmetic products to consumers.

TOPICS PROPOSED FOR INCLUSION INTO THE PROPOSED DRAFT REGULATION

It is the cosmetic industry in South Africa's belief that not all of the proposals made in our previous submission have been adopted, as the regulator foresees a graded approach to these requirements. We believe that this will form the premise for future ongoing updates that will address these areas. These areas include but are not restricted to, In-market control organization, Obligations of the responsible person, and associated definitions. We would like to offer to the regulator our expertise and proposals in the future re-imagining of regulatory solutions to assure constant consumer safety to match the rapid rate of innovation within the cosmetic industry.

Conclusion

We extend our gratitude to the Department of Health for affording the cosmetic industry of South Africa the opportunity to comment on the proposed redraft of the regulation.

We would like to re-iterate that our comments are representative of the cosmetic industry concerns, and are accompanied by objective proposals where alternative approaches are available that are likely to cause the least amount of disruption. These proposals are based mainly on our experience as an industry that has self-regulated for the past 20 years as well as expert opinion on local and international cosmetic industry best practice. We anticipate that these comments will receive due consideration in the finalisation of the regulation that will be enacted.

The CTFA remains available to answer further questions and provide detailed interpretation of our comments.

Yours Sincerely,

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CTFA Regulatory Affairs Manager

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