Cosmetic Snippets December 2017



FROM THE ED'S DESK

Dear CTFA Members

2017 has been an eventful year with many changes and updates in the legislative environment. From waste management, chemical management, biodiversity, cosmetic appliances to advertising, the environment has been a busy and evolving one.

In this issue of Cosmetic Snippets we focus on the Amnesty granted by the Department of Environmental Affairs and CTFA's role in this notable decision, CTFA's attendance at the International Organisation for Standardization (ISO) in Colombia and the registration process for cosmetic appliances. We also welcome Christie Fraser, the new Program Director for Look Good Feel Better. Look Good Feel Better's mission is to help women with cancer manage the appearance-related effects of cancer and its treatment. This is done with the assistance of donors, members, volunteers and partners like the CTFA.

Cosmetic Snippets is a quarterly newsletter to keep you abreast of what is happening in the regulatory landscape. This does not take away from the ongoing 'updates', 'notifications' and adhoc information sent to you during the year.

Thank you to all members for your ongoing support during 2017. The CTFA wishes you a safe and peaceful festive season with friends and family.

Kind regards.

Adelia Pimentel Executive Director

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DEPARTMENT OF ENVIRONMENTAL AFFAIRS -NATIONAL ENVIRONMENTAL MANAGEMENT: BIODIVERSITY ACT 2004, CHAPTER 6 – AMNESTY PERIOD

The CTFA and the industry at large have worked tirelessly to create trust and bridge the gap between industry and the Department of Environmental Affairs (DEA) in reaching alignment on BAB's regulations and requirements at individual and industry driven meetings and forums.

Bioprospecting permits remained a contentious issue in 2016 and 2017, with The Department of Environmental Affairs (DEA) Bioprospecting forum and work groups kicking-off in March of 2016. The forum focussed on understanding and aligning with industry, Traditional Knowledge Holders, the DEA mandate and all stakeholders' concerns and requirements. The four individual work groups focussed on best practice guidelines, a simplified regulation system, BABS permitting system and Traditional Knowledge and Benefit Sharing. These work groups delved into detailed discussions while tackling difficult and sensitive socio-economic, political and commercial aspects for alignment and resolution. The DEA indicated that the NEMBA Chapter 6 review and amendment process would be a long term plan with promulgation happening in 2019. The set-up of a multitechnical stakeholder task team will be required with intensive forum engagement. An expression of interest to serve on the technical team for amendment of Chapter 6 of NEMBA (National Environmental Management: Biodiversity Act 2004 (act No .10 of 2004) was sent out by DEA on the 16th of September 2016, for DEA team selection and notification.

The CTFA combined forces with other stakeholders in escalating industry concerns and requesting an amnesty from the minister to address the existing gap until NEMBA promulgation in 2019. This subsequently led to the Amnesty proposal being submitted to the Minister in June 2016. The DEA emphasized that Amnesty would be granted at the discretion of the Minister, was not a guaranteed outcome and the need for it to undergo legal and expert review prior to the Minister's approval. The DEA held a 5 week Bioprospecting Laboratory which culminated in the development of the BioPanza concept, which aims to establish a holistic and integrated approach with all parties involved in the Biodiversity and Bio-economy value chain.

DEA confirmed in November 2017, that the amnesty proposal was still under review due

to numerous concerns with the current status quo remaining in alignment with NEMBA.

During 2017 the CTFA embarked on an intensive campaign to engage and align DEA and industry by setting up one on one consultation sessions and partnering on roadshows in order to create industry awareness and identify specific concerns related to BABS. As a result a number of companies have begun engagements with DEA on matters related to BABS for resolution.

Prior to these initiatives the CTFA and industry were informed that the Amnesty was not guaranteed and that the industry's intention seemed to avert their accountability in terms of the regulatory requirements. However, these CTFA initiatives as well as other industry driven initiatives culminated in the publication of the Amnesty Notice 1155 on 1 November 2017; informing of The Ministers intention relating to a proposed amnesty period to facilitate the revision and compliance to Chapter 6 of NEMBA and BABS regulations. The notice further detailed the scope of the amnesty in terms of the affected person/ applicant, process, phase, requirements, related timelines and implications of noncompliance.

The proposed period of amnesty is 24 months from date of notice publication. The DEA has given due consideration and implemented a number of aspects that were put forth to them at various BABS forums, workgroups and individual engagement sessions; such as the twenty four month amnesty period and specific amendments to NEMBA which are currently under consideration. The Amnesty period will offer industry some reprieve to identify and negotiate Benefit Sharing Agreements with Traditional Knowledge holders, while the NEMBA Chapter 6 revisions are underway for promulgation in 2019.

DEPARTMENT OF HEALTH (DOH) PROMULGATION

As 2017 comes to a close the regulatory environment is still awaiting the much anticipated redraft of the Department of Health Notice 921 Foodstuffs, Cosmetics and Disinfectants Act, 1972 (ACT NO. 54 of 1972).





Department: Health REPUBLIC OF SOUTH AFRICA The Department of Health (DoH) confirmed that they are currently working on additional changes to the impending redraft of the DoH Regulations relating to the Labelling, Advertising and Composition of Cosmetics which is planned to be released for publication before the end of 2017. This publication will be followed by a second commentary period.

The department has announced that the second commentary period will be extended to 90 days from day of redraft publication.

The CTFA together with the industry at large is waiting for the publishing of the redraft and will be carefully analysing the content for commentary submission to the DoH.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO) COLOMBIA 2017 CONFERENCE FEEDBACK

The CTFA attended the ISO Plenary Meeting held in Cartagena, Columbia in October this year. Due to budgetary and timeline constraints no additional industry experts or South African Bureau of Standards (SABS) representatives were able to attend.

The honour was bestowed on the CTFA to represent the nation and to position the industry in the various workgroups mentioned below:

WorkGroup1 (WG1) - Microbiology focussed on the review of 21322: On - microbiological testing of impregnated or coated products draft document, where the WG aligned on revising the document title and scope to focus solely on wipes and masks. This decision was taken in order to align the methodology contained in the draft document to specific product types. The WG further discussed ISO/WD 11930: Cosmetics-Microbiology-Evaluation of the antimicrobial protection of a cosmetic product where Japan presented test data indicating significantly improved results based on methodology optimisations. Specific countries indicated that the standard was in use for a number of years with great results. Experts recommended additional laboratories to conduct the test protocol in order to correlate test results prior to aligning on standard revision.

It was also agreed that the banning of Triton multiplied by 100 currently in use and referenced in the ISO Microbiological standards and the future inclusion of clauses into standards to ensure adherence to all aspects of ISO standards and not partial alignment, could mislead industry.

WG3, The Analytical Methodology workgroup confirmed that ISO/DTR 18811 Cosmetics - Guidelines on the stability testing of cosmetic products had been sent for publication at the beginning of September and is pending publication. Measurement of traces of heavy metals in cosmetic finished products for Mercury (using DMA-Direct Mercury Analysis), ring trial results were discussed with the results being comparable to other currently existing Mercury analysis methodology results. Locally, Merieux NutriSciences participated in the ring trial and will together with other participating laboratories be valorised in the scientific article to be developed for publication. Further discussions were held on ISO and CEN potential partnership in developing a standard for Mercury analysis using other methodologies such as AAS which will be considered by the workgroup moving forward.

WG7, on Sun Protection Methods was a very active group with a number of ring trials being conducted for ISO/NP 24444 Cosmetics - Sun protection test methods – In vivo determination of the sun protection factor (SPF) and water resistance. Discussions were held on the new standard sample development and criteria for ring trials. Cosmetics Europe presented data from studies conducted on currently marketed products, which will form the acceptance criteria for the evaluation of results obtained from sun protection methods being modified, developed and alternative methods developed for human (volunteer) safety and ethical considerations.

An alternative methodology currently underway is the HDRS (Hybrid Diffuse Reflectance Spectroscopy), requiring the use of specialised Diffuse-Reflectance Spectroscopy equipment to provide in vitro and in vivo (hybrid) SPF results. HDRS would potentially have additional benefits in terms of cost efficiencies by testing between eight to ten product samples in an hour, using a single product sample for analysis and results for SPF, UVA and critical wavelength values. This alternative amongst others currently being developed would offer an ethical and safe alternative to the in vivo test methods currently being utilised globally.

Developments, publication and potential local adoption of these standards will impact local testing facilities and potentially have ripple effects on industry at large *in the future*.

COSMETIC APPLIANCES/ EQUIPMENT REGISTRATION PROCESS

Due to the increasing need from our members to address cosmetic devices requirements, the CTFA has researched the applicable regulations pertaining to cosmetic electrical equipment for use at home or at professional salons.

The relevant technical regulation is VC 8055: Compulsory Specification for the safety of electrical and electronic apparatus, and the standard is IEC 60335-1, which are both available on the CTFA website, inside login.

The requirements include registration of the company with the Electrotechnical Division of the NRCS, which requires details of the responsible person who will act on behalf of the company to load all applications/ service. This is followed by an application for a letter of authority which has several prerequisites to complete the process. Some of these requirements include, an IEC safety test report which is not older than 3 years and which is issued from an accredited laboratory; the device must be tested to the latest edition of the relevant standard; a picture of the device. The relevant forms and further supporting information and documents can be accessed on the CTFA website for further assistance.

There is a compulsory levy that is applicable and payable to the NRCS as devices form part of regulated goods. The levy period A is for the period January to June, and period B to take place from July-December.

The levy is calculated as follows:

The quantity of devices imported X the relevant tariff in a specific period. Details on the levies can be found on the CTFA website.

REACH REGISTRATION DEADLINE 31 MAY 2018

Do you export chemicals to the European Economic Area in quantities of more than 1 ton per annum?

REACH is a regulation of the European Union (EC 1907/2006), aimed at improving the protection of human health and the environment through better and earlier identification of the intrinsic properties of chemical substances. This is done by the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals. REACH also aims to enhance innovation and competitiveness of the EU chemicals industry.

Non-EU companies are affected by REACH if they export chemicals to the EEA in quantities of more than 1 ton per year. Non-EU companies that export to the EU cannot register substances themselves, but their EU-based importers must do that. To complete the registration dossier, the EU-importer will need detailed information on the composition and the properties of the chemical substance, which will need to be provided by the non-EU company. Alternatively, the non-EU company can also appoint a so-called "Only Representative", who must be based in the EU, to submit the registration on his behalf. In both cases, the non-EU company must be prepared to provide the information that is required for the registration. Companies that need to register

the same substance must share data and related costs and submit most of the information jointly.

Adopted in December 2006, REACH reversed the burden of proof on the safe use of chemicals. It is now up to companies to demonstrate that the chemicals they manufacture or import in the EU can be used safely and do not cause unacceptable risk to human health and the environment. The companies' findings and conclusions are recorded in a registration dossier that is submitted to European Chemicals Agency (ECHA). The information in the registration dossiers is used for further regulatory processes and published on the ECHA's website. This helps European and non-EU companies, authorities and citizens to make informed decisions on chemicals they use or that they may be exposed to.

Please visit the ECHA website for extensive information on REACH and other EU chemicals legislation- https://echa.europa.eu

The final date for registering chemical substances under the EU chemicals legislation REACH: **31 May 2018**. After that date, substances produced or



imported in quantities reaching one ton or more per year per manufacturer or importer that are not registered with the ECHA can no longer be placed on the EU market.

CTFA 2018 RENEWAL FORMS



THANK YOU to all Members who have thus far submitted their Renewal Membership Application forms. The updated membership forms are an absolute must to ensure that your details are kept up to date on our database, which in turn ensures that you receive all CTFA notifications and are kept updated on changes in the legislative environment.

The Renewal Membership Application forms assist the CTFA with invoicing, which will be done at the end of January 2018. Just a reminder that all members will be entitled to an "Early Bird Discount" if the invoice is paid by the 1 April 2018.

According to the POPI Act your details are kept confidential and not shared with any third party.

WHY CTFA MEMBERSHIP?

The current regulatory environment is constantly changing. The myriad of changes in the various legislative areas, the pending redraft of the Department of Health regulations and the migration of a self-regulated to a regulated environment are all areas that have been with us this year. CTFA can assist you in navigating through the maze.

Your CTFA Membership can be seen, not only as a valuable asset to your company but also as:

- an 'insurance policy' enabling compliance at all levels of the value chain
- a confidential base to sound out regulatory issues
- a source providing advance warning of legislative regulatory change to keep you ahead of competitors
- the industry voice, presenting the industry as reputable and responsible and dealing with issues in a brand-neutral manner
- a provider of documentation in the form of Certificates of free Sale that aids Members with export consignments
- an opportunity to participate on Working Groups/Committees who develop Standards, in conjunction with South African Bureau of Standards, Department of Health using International norms.
- An industry representative, negotiating with government departments; Department of Health, Department of Trade and Industry, Department of Environmental Affairs, Treasury, amongst others.
- An opportunity to be part of the decision-making process that shapes the regulation and representations that are made from time to time on behalf of the cosmetic industry

- a base providing individual technical advice and guidance
 - our experienced technical staff are ready to provide confidential advice on regulatory issues relating to ingredients and packaging claims
 - our technical team is available to meet with Members and/or potential members on a one-to-one basis to engage and find solutions to specific concerns
 - our technical team reviews and reports on artwork with reference to the Regulatory Environment

Please contact us on **info@ctfa.co.za** or set up a face-to-face meeting, to ensure you maximise your CTFA membership on an ongoing basis.



CTFA DRIVES IN THE LEGISLATIVE ENVIRONMENT

2017 has been an incredibly busy year, with many milestones being achieved, 2018 promises to be just as busy with a myriad of projects to either be finalized or evolving to the next level.

Stakeholder engagement will once again have to take center stage in ensuring that the CTFA challenge and engage the relevant authorities and stakeholders to assure the positive outcome required by industry. These engagements will be mandated by you, the members, to ensure enabling outcomes for the cosmetic industry and overall economy.

• Waste Management Plans and Pricing Model

Consumer Goods Services Ombuds - Pricing

optimisation of various standards

The South African Bureau of Standards (SABS) -

NRCS - Metrology Bill

ISO global participation

Model

Herewith a list of some projects that the CTFA are currently involved in and will continue to be so in 2018:

- Department of Health (DOH) Cosmetic Regulations
- The National Environmental Management Biodiversity Act (NEMBA)
- BABS permits and amnesty
- Advertising Standards Authority of South Africa (ASASA) Advertising code

We look forward to 2018 with the aim to grow a sustainable legislative environment for all.

- International Cooperation on Cosmetics Regulation (ICCR)
- Adhoc workgroup projects
- Mercury Study
- Relaxer study
- Chemicals management

WELCOME NEW LGFB DIRECTOR

We would like to welcome Christie Fraser as the new National Program Director at Look Good Feel Better (LGFB).

Christie's career spans 23 years, which started off as a Foundation Phase educator in a main stream school and then later at a school for children with severe disabilities. It is here where she combined her love for horses and education by qualifying as an Equitherapist (who through combining occupational therapy and horse-riding provides therapy for people with disabilities).

When moving to Johannesburg from the Free State she traded education

for sales in the corporate world. First with Aspen where she was Sales Representative of the Year for 5 consecutive years and then later with Nampak.

Christie has experience in key account management, sales and quality control. She is a self-driven people's person with passion and determination. Her strongest attribute is probably empathy and her ability to get on with all walks of life. Christie is married and her daughter starts university next year. We are delighted Christie is heading the Look Good Feel Better team, and we greatly look forward to working with her in her new role as National Program Director.



Christie Fraser



CTFA TEAM AT YOUR SERVICE:

The service that CTFA provides to its members includes information sharing, regulatory advice, government stakeholder engagement, export and import legislative advice and assisting in overall industry compliance.

To deliver an effective service, staff with the relevant skills and attitude is a must. The CTFA has a dedicated, professional and motivated team that is always ready to be of service to each and every member.



From left to right: Elmarie Groeneveld – Accountant, Omphile Lehau – Membership & Development Officer, Dershana Valla – Regulatory Affairs Manager, Adelia Pimentel – Executive Director, Cindy Potgieter – Reception & Admin Support, Judy Nobin – Technical Manager

Adelia Pimentel

Adelia started at CTFA on 1 March 2016 and has the overall responsibility of leading the CTFA in delivering its industry mandate.

Judy Nobin Technical Manager

Judy has been with the CTFA from April 2015 and manages the full spectrum of regulatory compliance for multi-nationals, retailers and Associate Members.

Dershana Valla Regulatory Affairs Manager

Dershana started on 1 June 2016 and her portfolio includes the full spectrum of regulatory compliance for SMEs, which comprise 80% of the CTFA base.

Elmarie Groeneveld

Elmarie has been with the CTFA for the past 20 years, manages the CTFA accounts diligently and has a wealth of institutional knowledge.

Omphile Lehau Membership & Development Officer

Omphile started at CTFA on 1 June 2017 and her role is dedicated to all facets of membership, including retention, information sharing, member benefits and overall member experience.

Cindy Potgieter Reception & Office Support

Cindy assists with overall office support and is also the friendly voice that welcomes you to the CTFA when you phone in. Cindy started permanently at the CTFA on 1 March 2016.



2017 Year End Shutdown

The CTFA would like to take a moment, to thank each and every Member for your much appreciated support this year.

As we head into our twenty fourth year of business, we look forward to a continued, mutually beneficial, working relationship that will ensure the growth and success of our industry.

Please note that our offices will close on Friday 15th December 2017 and will re-open on Wednesday, 3rd January 2018.

We wish you a peaceful festive holiday season with friends and family.

Warm wishes from The CTFA Team

Adelia, Judy, Dershana, Elmarie, Omphile, Cindy

COSMETIC TOILETRY & FRAGRANCE ASSOCIATION OF SOUTH AFRICA

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