# ctfa news

COSMETIC TOILETRY & FRAGRANCE ASSOCIATION OF SOUTH AFRICA

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## FROM THE ED'S DESK

Dear CTFA Members

In the midst of the current COVID-19 global pandemic, business is trying to survive in very uncertain times. CTFA continues to be available to member companies for advice and dissemination of information. Please feel free to phone or email us should you require assistance.

This issue of CTFA News provides information on the current status of hand sanitiser. Although they do not fall within the ambit of cosmetics, the Department of Health has provided industry with some clarity from a regulatory perspective.

"Cosmeceuticals" is a term that is used globally, in this issue we define it and explore the regulatory framework. Regulatory changes in Kenya will have a far-reaching impact for businesses with regards to imports and exports to and from Kenya. Included in this issue is an update on CTFA's involvement in mitigating the associated risks.

We also look at some frequently asked questions on Certificates of Free Sale (COFS), and remind you of Regulatory Alerts sent in Quarter 1 of 2020.

Thank you to all members for your ongoing support. Do keep safe and healthy.

Kind regards.

Adelia Pimentel
*Executive Director*

## COVID-19 NATIONAL LOCKDOWN - ESSENTIAL PRODUCTS AND SERVICES

**Following President Cyril Ramaphosa's announcement of a national lockdown to combat the spread of COVID-19, CTFA offices have continued to operate remotely, and normal working hours apply. Staff is available on email and by telephone to assist members with queries and dissemination of information. This ensures continuity of service delivery and the wellbeing of employees and stakeholders. In order to adhere to social distancing, meetings are conducted via Zoom or similar conference facilities.**

At the start of lockdown, CTFA sent an official request to the Minister of Economic Development, Minister Ebrahim Patel, to request the recognition of the cosmetic and personal care industry as "essential products and services" providers.

As a result, the list of essential products on Regulation Gazette No. 11062 Annexure B – Categorisation of Essential Goods and services during lockdown – Regulation 11A was duly amended to include personal hygiene products. These included:

*"(v) Personal toiletries, including haircare, body and facewashes, roll-ons deodorants, toothpaste"*

As from 1 May 2020 the country moved to Level 4 with a relevant 'Risk Adjusted Strategy'. Regulations were amended accordingly and the essential services/products for the cosmetic and personal care industry were widened to include more products:

*Annexure C:.*
*"Personal toiletries, including haircare, body, face, hand and foot care products, roll-ons, deodorants, dental care products."*

Companies that registered on the Government portal as suppliers of "essential products and services" providers are aware that this is done on a declarative basis and under the assumption that each company is respecting the definition, scope and nature of the definition of "Essential Products and services".

It is therefore the respective company's duty to respect the rules established by the Gazette. Transport regulations must also be strictly adhered to as per the Minister of Transport's official statement, outlining the times for movement of transport and operating shifts.

**Disclaimer**:
*As CTFA member companies, the above decisions are made at your own risk, with your own set of values, conscious of the facts and we cannot be liable for any actions made by the company.*

# HAND SANITISERS
## - A PRE-REQUISITE TO FACE COVID-19 CRISIS

**Following the President's declaration of a State of Disaster, various stakeholders have been tasked to help curb the impact of the COVID-19 virus in South Africa. Industry members have also responded to the need in a responsible manner by considering regulatory requirements of producing Hand Sanitisers to ensure that sufficient quantities of efficacious and safe products are available to assist in curbing the South African pandemic.**

CTFA has engaged with the Department of Trade and Industry (Dti), Department of Health (DOH), South African Bureau of Standards (SABS) and National Regulator of Compulsory Specifications (NRCS) on the topic of hand sanitiser. Various guidelines are currently available depending on the particular product application and claim made. Within the self-regulated framework of the cosmetic industry, the use of the product descriptor "sanitiser" does not meet the definition of a cosmetic as per the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act 54 of 1972).

The DOH referred CTFA to a position statement published by the Medical Control Council in 2016: "Status of Disinfectants, Antiseptics and Germicides" (9.78_Disinfectants_Antiseptics_Germicides_v1_Jul16). This document makes specific reference to standards that informs the requirements for disinfectants, antiseptics and germicides, including hand rubs and hand sanitisers.

An excerpt from this document and its interpretation from the DOH follows:

"Hand sanitisers in South Africa, do not fall under the ambit of cosmetics. They may be categorised into one of the ways shown below. The company must distinguish their product as either falling under the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act 54 of 1972) and the mandate of the Environmental Health Directorate within the Department of Health (DOH) or under the mandate of the Medicines Act, 1965 (Act 101 of 1965), and follow the requisite steps and abide by the relevant SABS Standard or NRCS specification." SAHPRA.

1. Sanitising products may fall into various regulatory groups depending on the:
    a. Application surface (human skin or inanimate surface)
    b. Environment the sanitiser is used in (place of use)
    c. Intended use and function; and
    d. Composition

2. Hand sanitiser is generally regarded as "Rub" or "Leave on" products primarily used to sanitise the skin, when soap and water are not available, and are left on and not rinsed off with water. These are controlled under the ambit of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) (FCD Act) and fall within the mandate of the Directorate: Environmental Health within the Department of Health.

3. Hand sanitisers must comply with the South African National Standard (SANS) 490:2013 "Disinfectant alcohol-based handrub", as well as the Trade Metrology Act, 1973 (Act 77 of 1973), in terms of packaging and labelling,

4. Disinfectants and germicides used on inanimate surfaces in low-risk areas within the home, public venues (schools, restaurants), health institutions, health professional consulting rooms and clinics are controlled under the ambit of the FCD Act, and fall within the mandate of the Directorate: Environmental Health within the Department of Health. These products must comply with the requirements of the "Compulsory specification for chemical disinfectants VC8054" as set out by the National Regulator for Compulsory Specifications (NRCS), the Trade Metrology Act, 1973 (Act 77 of 1973) as well as all relevant SANS standards.

5. Disinfectants, antiseptics and germicides used on inanimate surfaces in areas of high risk (hospital operating rooms, intensive care units (ICU), burn units, Cath Laboratories), are controlled as medical devices under the ambit of the Medicines & Related Substances Act, 1965 (Act 101 of 1965) (Medicines Act) as amended; and fall within the mandate of the South African Health Products Regulatory Authority (SAHPRA).

6. Disinfectants used to clean medical instruments are controlled as medical devices under the ambit of the Medicines Act as amended; and fall within the mandate of the SAHPRA.

7. Products primarily claiming to kill germs, disinfect or sanitise or using an active antimicrobial ingredient such as the hand sanitisers used in hospitals, are controlled as medicines under the ambit of the Medicines Act as amended; and fall within the mandate of the SAHPRA.

8. Antiseptic and anti-bacterial products specifically for use as surgical scrubs in operating theatres and used on human skin in hospitals' operating rooms, ICU, burn units, and cath laboratories which make claim to treat/ prevent infection are controlled as medicines under the ambit of the Medicines Act as amended; and fall within the mandate of the SAHPRA.

9. Where the intended use or claim for a product mentioned above lies both in a low risk area and a high risk area, the product will fall under the regulatory ambit of the Medicines Act as amended; and fall within the mandate of SAHPRA.

CTFA has engaged with the various stakeholders during this time of crisis. All the available information on hand sanitisers has been discussed with CTFA's technical committee and the relevant information has been disseminated to the industry. CTFA is also engaging with international industry associations to remain abreast with global practice to contribute to the shortage of hand sanitisers. Please refer to www.ctfa.co.za for regular updates.

# DEFINING THE TERM: "COSMECEUTICALS"

**The present day consumer can be described as informed and health conscious and in order to target these consumers, many cosmetic companies have chosen to promote the use of "cosmeceutical" products, a type of hybrid of cosmetics and pharmaceuticals, which claim to offer health benefits from using cosmetic products.**

Throughout history, many new terms and novel products have been introduced to the cosmetic industry, claiming to contain "miracle" ingredients which have the potential to transform what the beauty industry has to offer. The term "cosmeceuticals" is one such term that was set to change the way people experienced cosmetics. However, different countries in the world recognize the term in different ways, with many countries not categorizing such products as cosmetics due to a clear regulatory distinction between medicines and cosmetics. For this, considerations such as product claims and ingredients used are considered.

## THE HISTORY OF "COSMECEUTICALS"

The term "cosmeceuticals" in history was first coined in 1962 by Raymond Reed, a founding member of the Unites States Society of Cosmetic Chemists. The term was rooted in "science-based" cosmetics, as a way to provide cosmetics that were able to work to solve the medical problems of the skin, such as pH imbalances and inflammatory reactions. The concepts were also widely used in the field of anti-ageing. The attraction of the term for consumers is that it paints a picture that the cosmetics will not only be efficacious, but also based on science, much like pharmaceuticals. This combination of scientific principle, attention to clinical efficacy and beauty, directs the consumer's confidence that the product will not only serve its cosmetic purpose "on the surface", but function beyond the layers of the skin to promote skin health.

## REGULATORY FRAMEWORK: USA

The United States, Food and Drug Administration (FDA) states that the term "cosmeceuticals" is not in fact a recognized term, although they acknowledge the definition as cosmetic products that are said to provide a medicinal benefit (U.S Food & Drug Administration, 2018). In the USA, these products are not permitted, particularly because while medicines must undergo registration with the FDA, cosmetic products are not evaluated by the FDA and "are not intended to effect structure or function in the body" (U.S Food & Drug Administration, 2020). By virtue of this, "cosmeceuticals" are not are excluded from the cosmetic category.

## REGULATORY FRAMEWORK: EUROPEAN UNION

In the European Union (EU), the term "cosmeceutical" is considered borderline as a "functional cosmetic". Borderline products in the EU, are products which are not clearly defined in terms of whether it "is a cosmetic product under cosmetics legislation or whether it falls under other sectorial legislation". (Borderline products - Internal Market, Industry, Entrepreneurship and SMEs - European Commission, 2020). *"Guidance Document on the Demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83 as Agreed between the Commission Services and the Competent Authorities of Member States"* is helpful in understanding the clearly defined boundaries between the two areas. This document, available on the European Commission website, is a guideline and therefore not legally binding. However, one notable statement from this guideline document is that "a product may have a principal cosmetic purpose and also a secondary purpose to maintain health. A secondary preventative purpose does not exclude the classification of a product as cosmetic product". Thus, the EU maintains a "case-by case" approach for products of this nature, while not clearly defining "cosmeceuticals" in legislation (Borderline products - Internal Market, Industry, Entrepreneurship and SMEs - European Commission, 2020).

## REGULATORY FRAMEWORK: SOUTH AFRICA

South Africa's position on "cosmeceuticals" can be gathered from various guidelines. One such guideline is the Advertising Regulatory Board's Cosmetic Code of Practice (2019), which states that "the term "cosmeceutical" is not permitted with reference to cosmetic products. Similar terms are not allowed". Furthermore, *The Department of Health's draft Regulations Relating to Labelling, Advertising and Composition of Cosmetics, Government Notice R 1469 of 22 December 2017* under Regulation 9(e) on 'Product Claims' states that "claims that convey the impression that the cosmetic possesses medicinal properties is prohibited". With this being the stance in the South African self-regulated regulatory context, manufacturers and brand owners of such products should be weary of using terms such as these in reference to their products.

Although this trend continues to grow, and gain popularity globally, the regulatory framework of each country must be taken into serious consideration. Companies that intend to export products should check the regulatory guidelines in the country of question. In South Africa, ingredients that are not within the annexes of the draft regulations and CTFA Compendium, and claims that are medicinal as mentioned above will already exempt the product from being a cosmetic, regardless of the use of the term "cosmeceutical".

Companies should also be aware that regulations and guidelines, and each country's specific position on trends like these are ever-evolving and keeping up to date is important.

CTFA is the regulatory partner you can rely on to keep you updated on such changes.

**References**


*Advertising Regulatory Board (2019). Cosmetic Advertising Code of Practice.*

*Department of Health (2017). Government Notice R 1469 draft Regulations Relating to Labelling, Advertising and Composition of Cosmetics.*

*Internal Market, Industry, Entrepreneurship and SMEs - European Commission (2020). Borderline Products - Internal Market, Industry, Entrepreneurship And Smes - European Commission. [online] Available at: <https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en>.*

*International Journal of Clinical & Experimental Dermatology (2019). Cosmetics vs Cosmeceuticals Why to Choose Cosmeceutials?. 4(1) [online] Available at: < https://www.researchgate.net/figure/cosmetic- vs-cosmeceuticals-The-word-Cosmeceutical-was- invented-by-Raymond-Reed-and_fig1_301954168>.*

*U.S Food & Drug Administration (2018). "cosmeceuticals." [online] Available at: <https:// www.fda.gov/cosmetics/cosmetics-labeling-claims/cosmeceutical>.*

# KENYAN REGULATIONS OF COSMETIC PRODUCTS

**In January 2020, the Kenyan Ministry of Health (MOH) and Pharmacy and Poisons Board (PPB) published Draft Guidelines for Regulations of Cosmetic Products. Currently, Kenyan Bureau of Standards (KEBS) have imposed mandatory vertical standards on cosmetic products both locally manufactured and imported. This system poses many challenges for the cosmetic industry and CTFA's representation at the African Standards Organisation (ARSO) meeting in November 2019, strengthened our position on reconsidering these East African Standards (EAS) and to seek horizontal international standards that are more relevant from a product perspective as well as from an international trade position.**

By publishing the draft guidelines, the Kenyan MOH indicated a move to reform the regulatory system for cosmetics, but there were concerns that there may be a duplication of requirements.

CTFA is represented on the Sub-Saharan Task Force and worked with industry associations from USA and Europe to align on common comments and proposals represented from each jurisdiction's industry.

CTFA submitted a letter to the Kenyan MOH via the South African Embassy in Kenya before the end of the commentary period, 31 March 2020. Below is a copy of the letter submitted:

## COMMENTARY ON KENYA'S PROPOSED DRAFT GUIDELINES FOR REGULATIONS OF COSMETIC PRODUCTS

*"The Cosmetic, Toiletry and Fragrance Association (CTFA) is a national trade association representing over 80% of cosmetic companies in South Africa. These range from major multi-national cosmetic manufacturers and brands to medium and small companies. Industry members include companies who import and export products internationally, including Kenya.*

*As the industry association in South Africa, CTFA has overseen the self-regulatory system for cosmetics for 25 years. Our industry members are committed to the continued development of safe, innovative and efficacious products both for the local market as well as for products destined for export. South Africa is in the process of regulatory reform since 2016, when we saw the first draft of the Regulations Relating to Advertising, Labelling and Composition of Cosmetics, published by the Department of Health, on the 19th of August 2016 in Government Notice R 921. Through the efforts of the CTFA and engagement with the regulator on what as an industry we deem as best practice and key regulatory parameters required in an effort to enhance an industry that has thrived under self-regulation, the Department of Health published a second draft on 22 December 2017 in Government Notice R 1469.*

*As South Africa is part of a global community, we are in support of the Kenyan Ministry of Health's proposal to move towards reforming the regulatory environment for cosmetics. This will facilitate the promotion of safe products for consumers, both locally and internationally. We are supportive of the requirement to have a Responsible Person who is responsible for product safety and efficacy prior to placing the product on the market. We are also supportive of the regulator's intent to perform in-market control. These principles are based on international regulatory best practice and South Africa has based its draft regulations on similar international regulatory influences.*

*However, with the current regulatory system in place in Kenya through the Kenyan Bureau of Standards, our concern is on how the MOH envisions the draft guidelines to co-exist in the same environment. Though the current system of evaluating products using standards and the requirement of a third party testing and issuing a certificate of conformity, is not ideal and does not align to global practice, the proposed draft Guidelines will also not present a solution to the current problem of consumer safety. We are of the opinion that the draft guidelines will introduce complexity to the system which could prove to be detrimental to industry growth and increase trade barriers.*

*Superimposing the draft Guidelines on the current system will present local SMME's and other companies with the burden of extra administrative costs. This additional cost to company will be passed onto the retail price of products which could make products inaccessible from a price perspective for the local consumer. The proposed requirement for the registration of products will require that the Authority invest in additional time and resources to manage the large volume of registration applications. Furthermore, the requirement for product registration will result in a delay in placing product on the market ultimately affecting the local consumer. Such complexities may lead to noncompliant operators which may increase the presence of unsafe products in the market.*

*We propose that the content of the draft Guidelines be relooked considering the above concerns raised. As a country on the African continent and one that is currently in the process of reforming, we understand first-hand the challenges faced by our markets. We believe we are well positioned to offer proposals on introducing a regulation that would allow the Kenyan market to thrive as well as facilitate trade with international countries and simultaneously function to ensure safe and efficacious products for the local consumer. We would like to suggest that the South African draft Regulations relating to Labelling, Advertising and Composition of Cosmetics, R 1469, 22 December 2017, be considered as a template in an effort to subscribe to an incremental approach that will ensure local compliance through compliance and transition periods that will consider Kenya's specific local requirements.*

*The South African cosmetic industry members have submitted commentary on the Kenya Draft Guidelines for Regulations of Cosmetic Products to the Kenyan Association of Manufacturers (KAM) for collation with local commentary. The South African Department of Trade and Industry (the Dti) supports CTFA and the local industry's position and comments. We extend our gratitude to the Ministry of Health in Kenya for affording the South African industry association the opportunity to comment on the proposed draft Guidelines.*

*CTFA remain available to provide further detailed information in this regard."*

# INTERNATIONAL FRAGRANCE ASSOCIATION
## - 49TH AMENDMENT TO IFRA'S STANDARDS

**The International Fragrance Association (IFRA) is a global industry association that aims to ensure consumer safety of fragrances and fragrance-containing products. IFRA's members include national associations from around the world and South Africa is represented by the South African Association of the Flavour and Fragrance Industry (SAAFFI). Since fragrances are used as a component of various products, beyond perfumes and body sprays, many manufacturers and brand owners alike may benefit from understanding the standards involved in IFRA's self-regulated Code of Practice.**

### IFRA'S CODE OF PRACTICE & STANDARDS

IFRA's Code of Practice contains a set of standards, which are based on scientific research and risk-based assessments conducted by a panel of experts, also known "The Expert Panel for Fragrance Safety" (ifrafragrance.org, Code of Practice). This panel reviews the activities of the Research Institute for Fragrance Materials (RIFM) and through consideration of all safety aspects and latest scientific developments, makes a decision regarding what is necessary for consumer and environmental safety. If determined that a restriction of use is necessary, an IFRA Standard will be published. Amendments to such a document must thus be understood, as the impact to the industry may be significant. Resulting standards and amendments often lead to restrictions in the maximum allowed limit of fragrance materials, which IFRA "expresses as an upper concentration of fragrance material in the finished consumer product". It is imperative that suppliers of fragrance materials keep manufacturers informed of updates, as mixtures of restricted materials may only be used up to the maximum allowed concentration.

### NOTIFICATION OF THE 49TH AMENDMENT

In order to update our members on recent developments, in January CTFA notified members of IFRA's 49th Amendment to it's Code of Practice:

*On 10 January 2020, the International Fragrance Association (IFRA) notified the public of a 'Notification of the 49th Amendment to the IFRA Code of Practice'.*

### IFRA'S 49TH AMENDMENT: SAFETY STANDARD UPDATES AND CONSIDERATIONS

The 49th amendment included the following updates: 25 new standards; changes to the more than 100 existing standards; an increase in coverage of ingredients to 214 (ifrafragrance.org, Updating).

Among the standards, the following have been identified as key considerations to be made by fragrance companies:

1. New standards for dermal sensitisation, called Quantitative Risk Assessment (QRA2).
2. Increase in the number of product categories, along with new sub-categories
3. Revised phototoxicity considerations
4. Aggregate exposure of fragrance ingredients.

#### *Quantitative Risk Assessment (QRA2)*

Dermal sensitization is common with fragrance ingredients, and therefore formulating these products at safe levels is vital. "Based on the chemical, cellular and molecular understanding of dermal sensitization, it is possible to conduct an exposure-based Quantitative Risk Assessment (QRA) to determine safe use levels of fragrance ingredients in a variety of consumer product types." (ifrafragrance.org, Guidance for the Use of IFRA Standards). The new methodology, QRA2, encompasses the latest scientific findings.

#### *Phototoxicity Considerations*

Compared to the previous Amendments, the IFRA 49th Amendment introduces the following changes:

- Introducing a restriction level to rinse-off products in the Standard of Tagetes oil and absolute.
- Subcategorization of Category 7 in A and B to take into account the presence of rinse-off and leave-on products included in this category. Category 7 contains leave-on (7A) and rinse-off (7B) products for which phototoxicity considerations are applicable.
- Consideration of potential phototoxicity for all product types included in Category 8 (even if there is no expected exposure to sunlight).
- Subcategorization of Category 11 in A and B to take into account the presence of rinse-off and leave-on products included in this category.
- (ifrafragrance.org, Guidance for the Use of IFRA Standards)

Please refer to the table on the next page, which aims to further specify the product categories and restrictions applicable:

*Table 6 from 'Guidelines for the Use of IFRA Standards': Outline of the revised rationale on phototoxicity considerations introduced with the 49th Amendment and its application to the Standards of Tagetes oil and absolute and Methyl N-methylanthranilate.*

| CATEGORY | PRODUCT TYPE | PHOTOTOXICITY CONSIDERATIONS | RESTRICTION FOR TAGETES OIL AND ABSOLUTE[1] | RESTRICTION FOR METHYL N-METHYLANTHRANILATE[2] |
|---|---|---|---|---|
| 1 | Products applied to the lips | Applicable (leave-on) | 0.01% | 0.1% |
| 2 | Products applied to the axillae | Applicable (leave-on) | 0.01% | 0.1% |
| 3 | Products applied to the face/body using fingertips | Applicable (leave-on) | 0.01% | 0.1% |
| 4 | Products related to fine fragrance | Applicable (leave-on) | 0.01% | 0.1% |
| 5 Products applied to the face and body using the hands (palms), primarily leave-on: | | | | |
| 5A | Body lotion products applied to the body using the hands (palms), primarily leave on | Applicable (leave-on) | 0.01% | 0.1% |
| 5B | Face moisturizer products applied to the face using the hands (palms), primarily leave on | Applicable (leave-on) | 0.01% | 0.1% |
| 5C | Hand cream products applied to the hands using the hands (palms), primarily leave on | Applicable (leave-on) | 0.01% | 0.1% |
| 5D | Baby Creams, baby Oils and baby talc | Applicable (leave-on) | 0.01% | 0.1% |
| 6 | Products with oral and lip exposure | Applicable (leave-on) | 0.01% | 0.1% |
| 7 Products applied to the hair with some hand contact | | | | |
| 7A | Rinse-off products applied to the hair with some hand contact | Applicable (rinse-off) | 0.1% | No Restriction |
| 7B | Leave-on products applied to the hair with some hand contact | Applicable (leave-on) | 0.01% | 0.1% |
| 8 | Products with significant anogenital exposure | Applicable (leave-on)[3] | 0.01% | 0.1% |
| 9 | Products with body and hand exposure, primarily rinse off | Applicable (rinse-off) | 0.1% | No Restriction |
| 10 Household care products with mostly hand contact: | | | | |
| 10A | Household care excluding aerosol products (excluding aerosol/spray products products) | Applicable (rinse-off)[4] | 0.1% | No Restriction |
| 10B | Household aerosol/spray products | Applicable (leave-on) | 0.01% | 0.1% |
| 11 Products with intended skin contact but minimal transfer of fragrance to skin from inert | | | | |
| 11A | Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate without UV exposure | Not applicable (leave on without UV exposure)[5] | No Restriction | No Restriction |
| 11B | Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate with potential UV exposure | Applicable (leave-on) | 0.01% | 0.1% |
| 12 | Products not intended for direct skin contact, minimal or insignificant transfer to skin | Not applicable (non-skin contact) | No Restriction | No Restriction |

*1 The upper concentration level allowed by the IFRA Standard for Tagetes oil and absolute is 0.01% in leave-on products and 0.1% in rinse-off products.*

*2 The upper concentration level allowed by the IFRA Standard for Methyl N-methylanthranilate is 0.1% in leave-on products. There is no restriction applicable to rinse-off products.*

*3 Potential phototoxic effects are taken into consideration for Category 8 (Products with significant anogenital exposure), for reasons of conservativism to take into account some uses of the products that could include UV exposure (e.g. baby wipes).*

*4 Category 10A includes rinse-off products and products with limited skin contact. As a conservative approach, all the products included in Category 10A are treated as rinse-off products for phototoxicity considerations.*

*5 Category 11A contains products which are applicable to the skin but without UV exposure. As a consequence, the applicability of phototoxicity considerations becomes irrelevant for the products of Category 11A. (ifrafragrance.org, Guidance for the Use of IFRA Standards)*

***Aggregate Exposure of Fragrance Ingredients***

A consideration made within this update is the "aggregate exposure" of fragrance ingredients (i.e. the combined effect of different products used on the same place). Oral care products are a particular focus, as the "49th Amendment implies that simultaneous usage of e.g. a toothpaste and a mouthwash (two products from the same category) is assessed, but not the concomitant use as a flavour ingredient in food"

### COMPLIANCE PERIOD FOR NEW FRAGRANCE PRODUCTS

New fragrance products, according to the 49th Amendment, will have until the 10th of February 2021 to comply to the new standard updated. This is said to include any "fragrance mixture for which the brief has been issued after the completion of the information exchange across the supply chain period". This refers to any fragrance-containing product that began development after the notification of the amendment was communicated by IFRA

### COMPLIANCE PERIOD FOR EXISTING FRAGRANCE PRODUCTS

Existing fragrances, according to the 49th Amendment, have until 10 February 2022 to comply to the amendment, allowing a two-year transition period. Existing fragrances refer to products that have already been placed on the market previously, or were already in development when the notification was communicated by IFRA. This includes mixtures that were in development by either the fragrance manufacturer or the product manufacturer.

### AVAILABILITY OF THE GUIDELINES

The 'Notification of the 49th Amendment to the IFRA Code of Practice', as well as the IFRA Standards have been published on the IFRA Website: https://ifrafragrance.org/safe-use/standards-guidance.

The document 'Guidelines for the Use of IFRA Standards', on which this article was based, is also available on the IFRA website. All manufacturers and suppliers of fragrance products are encouraged to familiarise themselves with the changes.

CTFA will also strive to assist our members in navigating the standards, and will keep members informed of any future updates.

*References*

*Ifrafragrance.org. 2020. Code of Practice. [online] Available at: <https://ifrafragrance.org/safe-use/code-of-practice-new> [Accessed 1 April 2020].*

*Ifrafragrance.org. 2020. Guidance for the Use of IFRA Standards. [online] Available at: <https://ifrafragrance.org/docs/default-source/ifra-code-of-practice-and-standards/49th-amendment/ifra-49th-amendment-(att-01)---guidance-for-the-use-of-ifra-standards.pdf?sfvrsn=f83d57c7_3> [Accessed 1 April 2020].*

*Ifrafragrance.org. 2020. Introduction. [online] Available at: https://ifrafragrance.org/what-we-do/introduction*

*Ifrafragrance.org. 2020. Updating Our Flagship Safe Use Program. [online] Available at: <https://ifrafragrance.org/safe-use/introduction-enjoy-confidence/updating-our-flagship-safe-use-program>*

# SUMMARY OF REGULATORY ALERTS FOR QUARTER 1 OF 2020

**The following provides a summary of some of the global regulatory alerts that CTFA shared with members in Q1 of 2020:**

| DATE OF ALERT | REGULATORY ALERT | PROPOSED DATE OF ADOPTION/ COMMENTS | IMPACT FOR SOUTH AFRICAN INDUSTRY |
|---|---|---|---|
| 3 January 2020 | The China State Council passed the draft Cosmetic Supervision and Administration Regulation (CSAR), which aims to ensure quality and safety of cosmetic products as well as to promote industrial development within the industry.<br><br>The CSAR will replace the Cosmetics Hygiene Supervision Regulations (CHSR). | Date unconfirmed | Relevant for those companies exporting cosmetic products to China.<br><br>Changes include:<br><br>- Special-use cosmetics categories<br>- Safety assessment report requirements<br>- Literature review and test report requirements<br>- Risk-based regulations for cosmetic products and ingredients<br>- Pre-market notification for non-special-use cosmetics and pre-market registration for special-use cosmetic. |
| 8 January 2020 | The National Institute of Metrology, Quality and Technology (INMETRO) (Brazil) notified of Draft Regulation 758, which proposed the updating of the technical requirements for the labelling of personal hygiene products, cosmetics and perfumes. | In the date of its publication | Relevant for those exporting cosmetic products to Brazil.<br><br>Changes may include:<br><br>1. Redesign of labelling according to labelling requirements |

| DATE OF ALERT | REGULATORY ALERT | PROPOSED DATE OF ADOPTION/ COMMENTS | IMPACT FOR SOUTH AFRICAN INDUSTRY |
|---|---|---|---|
| 10 January 2020 | The International Fragrance Association (IFRA) published a 'Notification of the 49th Amendment to the IFRA Code of Practice'. | Companies with new fragrance products will have until 10 February 2021 to comply with the new standards, while existing fragrances have until 10 February 2022 to comply. | Relevant for those manufacturing fragrance- containing products.<br>The impact to the industry may include reformulation in order to comply.<br><br>The upgrade to ingredient safety standards includes the following methodologies:<br><br>1. New standards for dermal sensitization, based on Quantitative Risk Assessment (QRA2), a new methodology<br>2. Aggregate exposure of fragrance ingredients (i.e. the combined effect of different products used on the same place) |
| 22 January 2020 | The Department of Environment, Forestry and Fisheries (South Africa) published a Notice of Withdrawal of the Section 28 Notice Calling for Paper and Packaging Industry, Electrical and Electronic Industry and Lighting Industry Waste Management Plans. | The deadline for inputs was set as 24th January 2020. | The withdrawal of the notice means a new process, under Section 18, will drive the waste management plans towards an industry-managed plan |
| 7 February 2020 | The Ministry of Food and Drug Safety (Republic of Korea) notified of proposed amendments to the Enforcement Rule of the Cosmetics Act. | In the date of its publication | Relevant for those exporting cosmetic products to Korea.<br>Changes may include:<br>1. Redesign of labelling with regards to claims<br>2. Wording must be changed from "functional cosmetics that help relieve dry skin caused by atopic dermatitis" to "functional cosmetics that help ease itchy skin by supporting the recovery of skin barriers" |
| 19 February 2020 | Department of Chemicals and Petrochemicals, Government of India (India) notified that locally manufactured or imported Potassium Carbonate Anhydrous must conform to the Indian standard (IS 7129: 1992) and bare the standard mark under license from the Bureau of Indian Standards (BIS). | In the date of its publication | Relevant for those exporting cosmetic products to India.<br>Changes may include:<br>1. Reformulation according to minimum purity and percentages outlined |
| 26 February 2020 | Environmental Protection Agency (EPA) (United States of America) is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances which are the subject of premanufacture notices (PMN). | | This action would require persons to notify EPA at least 90 days before commencing manufacture or processing of any of these chemical substances for an activity that is designated as a significant new use by this proposed rule.<br><br>This action would further require that persons not commence manufacture or processing for significant new use until they have submitted a Significant New Use Notice, and EPA has conducted a review of the notice, made an appropriate determination on the notice under TSCA 5(a)(3), and has taken any risk management actions as are required as a result of that determination.<br><br>Relevant for those exporting products to the USA (as imports are included as substances which will be required to notify EPA).<br>This may cause delays in placing products on the USA market, or reformulation should the review by EPA require this. |
| 27 February 2020 | Department of Agriculture, Water and the Environment (Australia) notified of a National Standard developed by all Australian governments to efficiently and effectively manage the impacts of industrial chemicals on the environment, while providing consistent requirements for businesses. The National Standard will be established by a legislative framework consisting of primary legislation and subordinate legislative instruments. | Final date for comments is 27 April 2020 | Relevant for those exporting products to Australia. |
| 12 March 2020 | The European Commission (European Union) notified of the Draft Commission Regulation amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. | Proposed date of adoption is the 4th quarter of 2020.<br><br>Final date for comments is 12 May 2020. | The aim: allow the use of Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate as a UV filter in cosmetic products at a concentration up to 3%, by adding it to the list of authorised UV filters in Annex VI.<br><br>This will not be added to Compendium Annexes until it is published in the Official Journal of the EU. |

| DATE OF ALERT | REGULATORY ALERT | PROPOSED DATE OF ADOPTION/ COMMENTS | IMPACT FOR SOUTH AFRICAN INDUSTRY |
|---|---|---|---|
| 12 March 2020 | The European Commission (European Union) notified of the Draft Commission Regulation amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. | Proposed date of adoption is the 4th quarter of 2020.<br><br>Final date for comments is 12 May 2020. | The draft measure proposed to ban three substances for use in hair dye products due to their potential genotoxicity and mutagenicity found by the EU Scientific Committee on Consumer Safety (SCCS).<br><br>The draft also proposes to restrict in Annex III to the Cosmetics Regulation the maximum concentrations of six substances for use in hair dye products and of one substance for use in products intended to colour eyelashes. |

If there are any further questions pertaining to the above listed alerts, please forward the questions to **info@ctfa.co.za.**

# BREXIT UPDATE

### TIMELINES

The United Kingdom left the European Union on 31 January 2020 with a Withdrawal Agreement. This meant that there would be a transition period from 1 February 2020 until at least 31 December 2020. During this transition period UK will not be have any participation or influence on any of EU's discussions and decision-making including the negotiations on the Free Trade Agreement (FTA) and Regulatory Cooperation, that are due to take place during the transition period. Currently, the UK Government has no intention of extending the transition period, even though the withdrawal agreement makes provision for a once off extension for up to 2 years provided the request is made by 1 July 2020. No extension of the implementation period will also mean that the FTA negotiations will end in November 2020. During the transition industry is expected to utilise the time to prepare for compliance with the new UK legislative framework which is yet to be agreed.

### NEGOTIATIONS

Negotiations are necessary for the following reasons:

- To secure a comprehensive UK/EU FTA which includes cosmetic products.
- To set UK-EU Regulatory Cooperation
- To avoid excessive regulatory divergences for cosmetic products
- The UK's Cosmetic, Toiletry and Perfumery Association (CTPA) has described the 3 possible scenarios as:
  **Scenario 1** – the transition period is extended This is least likely to occur and would allow more time to negotiate a FTA.
  **Scenario 2** – the transition period is not extended and an FTA is agreed . This is the most likely scenario and will result in the FTA negotiations only lasting approximately 6 months resulting in a bare minimum FTA.
  **Scenario 3** – the transition period is not extended and an FTA is not agreed. This scenario is possible but less likely to play out. If this goes ahead it will have the greatest impact on business as the FTA will not be agreed upon and WTO rules will be applicable to future trade and the Regulatory Co-operation may be agreed.

### TARIFFS

The mandate for negotiations is to maintain 0% tariffs for all goods traded between the UK and EU as well as Rules of Origin of goods to determine which tariffs apply. Currently, the UK Global Tariff plan has been published for public comments.

Customs: There will be no free movement of products between the UK and EU and proper documentation will be required for customs clearance.

### What will be expected from UK companies trading with the EU?

- UK companies must have a responsible person based in EU
- Product labels must be updated with new RP address
- Current CPNP notifications must be transferred to ne RP account
- Country of origin must be included if the products are manufactured in UK
- Current distributors may become importers

The UK notification database and how cosmetovigilance will be adopted are dependant upon the outcomes of the negotiations.

### WHAT ABOUT PRODUCTS THAT ARE ALREADY ON THE MARKET?

Article 41 of the EU Withdrawal Agreement states that goods placed on the EU27 or UK markets before the end of the implementation period may be further made available and circulate between the two markets until they reach the end consumer. For this to happen the proof of when the goods were placed on the market will be required.

### *REACH in the EU*

EU REACH will continue to apply to the EU27 Member States, as is currently the case.

After the transition period, UK companies selling in the EU27 will need to meet the following:

- re-calculate the tonnage band for substances sold in the EU27
- ensure the substances they are selling are registered under EU REACH
- if a registration is held by a UK company, it must be transferred to an EU entity
- current downstream users and distributors will become importers

### Registration, Evaluation, Authorisation and Restriction of Chemicals - REACH in the UK

REACH regulations will have to followed in the UK and some of the requirements are dependant on the outcome of the negotiations. And companies selling in the EU and UK will have to comply with both regulatory frameworks.

Chemicals that are currently NOT registered under the EU REACH will very likely have to register the substance under UK REACH.

Re-registration and the notification system with UK REACH of those chemicals that are already registered under EU REACH will depend on the outcomes of the negotiations.

### How to prepare for UK REACH?

Map the supply chain of the chemicals in your cosmetic product. You will need to find out whether the tonnage used is more than 1 ton and where the registration holder is based. You will also need to ascertain whether the registration holder or supplier plans to comply with UK REACH. Based on this your roles and responsibilities may change from a downstream user to an importer.

CTFA endeavours to keep a close eye on the developments in this arena. Please contact CTFA's regulatory experts if you have any further questions regarding trade with the UK post Brexit.

# PRODUCT LABELLING & SUBSTANTIATION TRAINING

**In keeping with CTFA's role to encourage compliance and to increase awareness and understanding of the Department of Health (DOH) Government Notice R 1469 draft Regulations Relating to Labelling, Advertising and Composition of Cosmetics, 22 December 2018, CTFA conducted its first training of 2020, "Product labelling, Product claims and Claim substantiation". The first session was held at CTFA's offices in Hurlingham in February. The training was well attended.**

### PRODUCT LABELLING:

CTFA's Head: Policy and Regulatory Affairs, Dershana Valla, unpacked the requirements for labelling within the current regulatory framework, which includes a mandatory standard: SANS 289: Labelling Requirements for Pre- packaged Products (pre-packages) and General Requirements for the Sale of Good subject to Legal Metrology Control, under the ambit of the National Regulator for Compulsory Specifications (NRCS); SANS 98: Ingredient labelling of cosmetic products and the Department of Health Draft Regulations relating to labelling, advertising and composition of cosmetics, R.1469, 22 December 2017. The importance to comply with these requirements was emphasised with the objective of encouraging compliance as well as providing accurate information so that consumers are enabled to make informed purchase decisions depending on their specific predispositions.

### PRODUCT CLAIMS:

CTFA's Regulatory Affairs Officer, Yashmay Gordhon, impressed upon the Do's and Don'ts of product claims by providing clarity and guidance on claims that are permitted on cosmetic products. Clarification was provided on how to ensure that product claims fall within the scope of a cosmetic, and how to keep from misleading consumers with borderline claims. Specific product labels were used as practical examples to dispense the requirements, and emphasis was placed on claims that are unacceptable as per the Advertising Code of Practice, and the DOH Draft Regulations R1469. The session ended with an overview of upcoming regulatory changes, which will affect claims made on cosmetic products.

### SUBSTANTIATION:

Lastly, a guest speaker was invited from Sefako Makgatho Health Sciences University, School of Pharmacy, in Pretoria, Ms. Marlize Lategan. Ms. Lategan is responsible for the Photobiology Laboratory at the institution. She explained the importance of the accuracy and truthfulness of claim substantiation to ensure compliance with the draft regulations and the current Advertising Code of Practice. Ms Lategan elaborated on various scientific methods that are internationally accepted for specific claim testing, such as moisturising claims; sun protection factor (SPF) claims; anti-dandruff claims, to name a few. The laboratory issues reports that provide scientific substantiation for claims made and which form part of the product information file.

The two upcoming training sessions on the same topic, which were planned in Durban and Cape Town in April, have been postponed due to the circumstances of COVID-19. These sessions will be conducted at a later date to be communicated.

# CERTIFICATES OF FREE SALE

**CTFA aims to provide members with information on how to maximise benefits, by keeping you informed about services offered. One such service provided by CTFA is the issuing of Certificates of Free Sale (COFS), which is offered to members who wish to export their products. In order to assist you in deciding whether you require a Certificate of Free Sale, please refer to the following frequently asked questions.**

**1**

### WHAT IS A CERTIFICATE OF FREE SALE?

A Certificate of Free Sale provides assurance that the product(s) being exported from South Africa are being freely sold in the local South African market, meeting all Regulations and Standards that assure consumer safety requirements. Certificates of Free Sale are required in a growing number of countries.

**2**

### WHO MAY BE REQUIRED TO APPLY FOR A CERTIFICATE OF FREE SALE?

Companies exporting products from South Africa. Exports to certain countries need to be accompanied by a Certificate of Free Sale or a valid certificate or the product(s) may not be admitted, or cleared by customs at destination.

## 3 WHAT DO I REQUIRE TO QUALIFY FOR A CERTIFICATE OF FREE SALE?

In order to obtain a Certificate of Free Sale, CTFA expects that all South African regulatory guidelines have been followed. In order to ensure that this is the case, an artwork review of the products in question will be conducted by CTFA's regulatory department. If changes are required, the amendments must be made to the label and resubmitted to CTFA. Certificates of Free Sale will not be issued without relevant guidelines and regulatory requirements being met beforehand.

## 4 HOW DOES THE CTFA ISSUE A CERTIFICATE OF FREE SALE?

At the CTFA in the capacity, ex officio, the Executive Director, is duly authorised to sign Certificates of Free Sale for Member Companies attesting Member Company Registration and Membership Validation and the product list being exported. The Member requirement includes a Formal Undertaking and a list of products being exported.

Certificates of Free Sale are endorsed by the Department of Trade and Industry (Dti) and the South African Chamber of Commerce and Industry (JCI).

## 5 FOR HOW LONG IS A CERTIFICATE OF FREE SALE VALID?

A Certificate of Free Sale has an expiry of one year (12 months). After such time, the Member must reapply with all the requirements as mentioned above in point 3.

## 6 IS THERE A DEADLINE FOR APPLYING FOR CERTIFICATES OF FREE SALE?

In order to accommodate member requests before CTFA's annual shutdown, the deadline each year for applying for Certificates of Free Sale is the last working day of November (Monday, 30th November 2020).

Please also note the maximum lead time to process a COFS request is 4 weeks depending on the number of products to be reviewed and the amount of certificates requested by members. COFS are issued on a first come first served basis.

For any further questions or concerns regarding Certificates of Free Sale, please contact **info@ctfa.co.za.**

## CTFA CALENDAR – 2020

**DUE TO THE CURRENT COVID-19 PANDEMIC, DATES HAVE BEEN POSTPONED FOR THE MONTHS OF APRIL AND MAY 2020 AND OTHER DATES WILL BE REVISED ACCORDINGLY AS REQUIRED.**

**MAY 2020**
**28/05/2020 –** Technical Committee Meeting

**JUNE 2020**
**03/06/2020 –** Good Manufacturing Processes (GMP) Training
**19/06/2020 –** Department of Trade and Industry Meeting
**25/06/2020 –** Executive Committee Meeting

**JULY 2020**
**30/07/2020 –** Technical Committee Meeting

**AUGUST 2020**
**07/08/2020 –** Department of Trade and Industry Meeting
**19/08/2020 –** Product Information File Training

**SEPTEMBER 2020**
**10/09/2020 –** CTFA – IKW Safety Assessment Training
**10/09/2020 –** Technical Committee Meeting (TBC)
**17/09/2020 –** Executive Committee Meeting

**OCTOBER 2020**
**02/10/2020 –** Department of Trade and Industry Meeting
**14/10/2020 –** Induction Training for New Members

**NOVEMBER 2020**
**13/11/2020 –** CTFA Member Breakfast
**19/11/2020 –** Executive Committee Training
**27/11/2020 –** Department of Trade and Industry

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COSMETIC TOILETRY & FRAGRANCE ASSOCIATION OF SOUTH AFRICA

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