Cosmetic, Toiletry & Fragrance Association of South Africa – comments on the Guideline for Regulation of Cosmetic Products Rev. No. 0 dated June 2024

No.	Section of the Guidelines e.g. *Chapter 1 section 1.1*	Description of the issue including its impact	Proposed Change/Action	Justification – an explanation why the change is necessary
	General comments	1. Is the draft Guideline intended to replace the "Framework for the placement of cosmetic and related products into Kenyan market (Rev2)" document? 2. Use of inconsistent terminology creates confusion – e.g. Annex vs Annexure; "controlled cosmetics"; "special cosmetics"; "therapeutic cosmetics".	1. The new Guideline should indicate if it replaces it or the way forward for the framework document. 2. Please keep terminology consistent – for example, either use Annex or Annexure – not both words interchangeably. Please explain what "controlled cosmetics" means in the context of the classes of cosmetics.	1. A single regulatory framework would be ideal for cosmetics. This will streamline administration and operations and alleviate any confusion. 2. The use of terminology consistently will improve clarity.
	Comments of policy that relate to "Scope".	1. According to the existing Framework ("Framework for the placement of cosmetic and related products into Kenyan market (Rev2)"), PPB is responsible for regulating class 1 and 2 cosmetics, while KEBS is responsible for regulating class 3 cosmetics. The respective classes are as follows: 1. those with	1. Clarity is required in terms of the intention of how cosmetics are to be regulated in Kenya going forward and which frameworks/ legislations/ guidelines will apply. 2. Ideally, there should be a single regulator for cosmetics in Kenya with the definition of	1 – 3. Simplification and clarity regarding the regulatory environment for medicines and cosmetics, respectively, should be provided. Taking the above approach would streamline necessary administrative processes, decrease costs, and increase continental and international harmonisation in many cases.

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		medical/therapeutic claims - meeting both definitions makes it medicinal; 2. special and related products - these claim to prevent/interfere with normal operation physiologically; and 3. general cosmetics - not class 1 and not class 2 cosmetics limited to esthetics; texture; pH; colour; and smell. Is this still the intention of how cosmetics will be regulated in Kenya? 2. It is stated in the draft Guideline that under the Act "cosmetics" are included in the definition of "health product". This is confirmed to be the case. However, in the Act, cosmetics are not mentioned again specifically. It is however clearly provided for that the PPB is responsible for the regulation of health products (and therefore, by definition, cosmetics). However, under the functions of the Board there is no provision for a specific cosmetic function.	cosmetics excluding health-related products. There should be one definition for determining what a cosmetic is and another for a medicine, and so on. A hierarchy can be put in place from a regulatory perspective where if a product meets a definition of a medicine and a cosmetic, the medicine classification takes precedence (the product is deemed a medicine, not a cosmetic). Classes 1 and 2 alongside should then ideally not be considered as cosmetics. Cosmetics are generally not intended to have any function relating to health. The functions of the PPB in relation to the regulation of cosmetics should be clarified. Product-specific standards and regulation is contrary to most of the	

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		This creates confusion – the PPB has ultimate power from the Act to regulate cosmetics. However, there is no power in the Act for the PPB to undertake any cosmetic-related functions. 3. What is the status and progress with the development of the Kenya Drugs Authority Bill? This Bill is proposing to regulate "therapeutic cosmetics" that by definition include some common products generally viewed as being standard cosmetics. Are therapeutic cosmetics a new subcategory of class 1 cosmetics? The Bill could result in broad changes to the regulatory landscape for cosmetics in Kenya as well as confusion as to who regulates what aspect of cosmetics, and how cosmetics are considered.	international mechanisms in place for the regulation of cosmetics – this creates trade barriers for other countries wanting to provide cosmetic products to satisfy consumer demand in Kenya. 3. Please provide an update with respect to the development of the Bill and the intended way forward for the regulation of cosmetics in Kenya. Broad stakeholder engagements should take place on the Bill so that there is clarity on how cosmetics intend to be regulated as a country going forward.	
	1.0 - Introduction	1. The Pharmacy and Poisons Rules has its own definition of cosmetics. It is stated that	1. The Act should contain a single definition for "cosmetics" and for other	1. A single, appropriate definition of cosmetics should be used that does

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		the PPB is mandated by the Act. The Act has its own comprehensive definition of "health products" that include cosmetics. Having more than one meaning/scope of cosmetics - a term already subject to uncertainty if not adequately defined - could cause confusion and resulting delays.	categories covered (e.g. "medicines"), respectively.	not include products that have an impact on health.
	1.0 - Introduction	1. The Guideline's classification of cosmetics into two categories is not provided for by the Act.	1. Cosmetics as defined by the Act should not be categorised further. The definition for cosmetics should be clear, for example to exclude any medical-related cosmetic (by claim and/or active ingredient, for example).	The categorisation of cosmetics goes outside of the provisions of the Act and introduces confusion and red tape.
	1.0 - Introduction	Adoption of European Union directives should refer to European Union Regulations.	European Union Regulations should be directly referred to and a statement added about the frequency of updates of the Guidelines versus the coming into effect of new EU Regulations.	The proposed changes will result in regulatory alignment and clarity for stakeholders on expectations regarding implementation in Kenya.
	1.0 - Introduction	1. A statement is made regarding special cosmetics and the need to follow	1. Please include a statement that explains what "special cosmetics"	1. Stakeholders will be clear that the guidelines do not apply to special cosmetics,

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		regulations – this is taken to mean that special cosmetics are not included in the scope of this draft Guideline. 2. What is a "special" cosmetic – class 1, or 2, or 3, or a combination?	are and confirmation that this draft Guideline is not applicable to special cosmetics – if this is the case.	and what regulations to follow regarding "special cosmetics". 2. Stakeholders will be clear what "special cosmetics" are.
	1.1.1 - Regulation of cosmetic products	1. It is clarified that the PPB regulates various activities relating to "special cosmetics". However, the previous section alludes to there being Regulations. Is there a demonstrated need for there to be two categories of cosmetics and that "special cosmetics" require additional processes to be undertaken prior to marketing approval?	1. Please clarify in the previous section what these Guidelines are applicable to in terms of the type of cosmetics.	1. Clarity will be provided to stakeholders. 2. Further consideration of the principle of regulating "special cosmetics" differently is required to alleviate resource constraints.
	1.1.3 - Products from multiple sources	1. Separate registrations required for the same "special cosmetics" from different sources creates unnecessary burden on all.	1. An application should be able to state that there are multiple source locations of the same product, and then space can be provided on the application for the sites to be listed – on a single application form and using a single process.	1. This will reduce administrative and cost burdens for all. Reducing costs to MAHs will ultimately reduce consumer costs.

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	1.1.5 - Validity of registration	1. Throughout the document, "cosmetic" and "special cosmetic" are used interchangeably. This can create confusion. 2. The retention and full registration timelines are noted. A policy of requiring re-registration or amended registration should be considered to avoid unnecessary processes.	1. Please use only "special cosmetics" as this will reduce uncertainty. 2. Only if there are raw material or product changes should a process be required to be undertaken. If nothing has changed then there should be no need to redo the registration, as long as the safety assessments are current (discussion needed in terms of what "current" could mean).	1. Clarity for stakeholders and the scope of the Guideline. 2. Reduce administrative and cost burdens for all. Reducing costs to MAHs will ultimately reduce consumer costs.
	1.2 – Application procedure	1. While it is appreciated that product variants can be applied for using a single application, the requirement for separate fees for product variants is considered excessive.	1. Product variants should be considered as the same product with a single fee being applicable.	1. Reducing costs to MAHs will ultimately reduce consumer costs.
	1.2.2 – Contract agreement	1. "Authenticated" contract agreement – it should be stipulated what "authenticated" means and what the expectations of the Authority are. 2. Is it absolutely necessary for a local agent to be required?	1. A contract agreement that has been authenticated by…. 2. If a company can handle its own affairs in Kenya without an agent and take responsibility, then it should be allowed.	1. Clarity will allow reduced reversions to applicants and more streamlined processes. 2. Costs will be reduced. Reducing costs to MAHs will ultimately reduce consumer costs.

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		This requirement increases costs.		
	1.2.3(ii) – Data on the manufacturer - Free Sale Certificates	1. Free Sale Certificates are not always immediately available, and this can delay applications and trade. 2. In South Africa, the responsible issuing body that provides Certificates of Free Sale is not the Health Authority, but the industry trade association CTFA.	1. It is requested that the Department of Trade, Industry and Competition-endorsed CTFA Certificates of Free Sale be acceptable to be submitted with applications. 2. The text should allow for other competent bodies to be recognized as issuers of FSCs, as is the case under 1.4(iii).	1. The proposed changes will alleviate any delays and misinterpretations.
	1.2.4 – Product composition information	1. As the draft Guideline is aligned to international regulations, it would be prudent to align ingredient listings in applications and labelling to INCI names. 2. Indicate the list of all ingredients, which will be present in the final product including the monograph reference, quantity and function. Providing the absolute quantities or concentrations risks a company's intellectual	1. Only INCI names should be used for ingredients. 2. A range in quantity should be allowed.	1. Additional international alignment will be achieved. 2. IP will be more protected if a range is provided.

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		property as products can be copied.		
	1.2.5 – Control of the finished product	1. Providing a list of mandatory tests for all types of cosmetics is not appropriate as some cosmetics may require fewer tests than others. 2. What is a "functional" cosmetic? This is yet another type of cosmetic listed in the draft Guideline which causes confusion.	1. Provide the list of all tests, but then indicate that not all tests will apply to all cosmetics. 2. Please indicate what a functional cosmetic is – this is a new word used. How does it relate to the classes and "special cosmetics" and "therapeutic cosmetics"?	1. The flexibility in mandatory tests will result in reduced costs as some tests will not be applicable to some cosmetics. 2. Please provide clarity or delete the new type of cosmetic.
	1.2.6. Method of Manufacture	1. Concise description of method of manufacture. This represents intellectual property, and the requirements are too proprietary (e.g. in-process controls)	1. Only require that facilities and processes are ISO 22716 (Good Manufacturing Practice) as this is sufficient to determine quality of process and end-product.	1. The detailed manufacturing process is intellectual property and GMP standard provides the required surety.
	1.3.2 - Variation	1. Any rejection of applications or variations should be accompanied by reasons. 2. Changes to products that result in a safer product should be treated as a variation rather than a new application.	1. Reasons should be stipulated along with the opportunity and process to resubmit the respective application. 2. Provisions should be made to allow changes to be made to result in safer products, at a reduced application processing fee.	1. This will forego rejection decisions being based on errors or correctable information. 2. There will be encouragement to find ever more safer ingredients for products.

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	1.3.3 – Application for retention; and 1.3.4 – Application for renewal	1. It is not clear what the difference between "retention" and "renewal" is. It seems they are different processes – why are they both required?	1. The difference between retentions and renewals should be expanded upon. Please consider if both processes are required and if so, please add these terms to the definition section as a minimum.	1. Reduced administrative processes and fees will streamline applications and products reaching market. 2. Increased clarity of terms will allow easier implementation of the requirements.
	1.4(ii) – Documents which must accompany application forms for registration of a cosmetic – certificate of analysis	1. What is expected for the "analytical assessment" requirement?	1. Please provide further information.	1. Further information will allow a comprehensive understanding of the requirements.
	2 – Classification of cosmetic products	1. Please refer to the comments under "Scope". It is understood that the PPB regulates "special cosmetics" only. While it is helpful to include a list of general cosmetics, it should be stipulated that the list does not fall under the products regulated by the PPB and the Guideline.	1. Please can the scope of regulation and the future intentions be clarified.	1. Clarification will result in those being regulated comprehensively understanding the scope of the different authorities.
	3.0(ii) – Labelling requirements – product category	1. What is meant by "product category"? In other sections of the Guideline there are different categories presented.	1. Please provide a list so that applicants can choose from the list.	1. Clarification of the categories will allow for more streamlined applications.

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	3.0(v) – Labelling requirements – expiry date / best used before	1. The Period After Opening should also be allowed to be stated if it is relevant for the type of product. Requiring the additional information may result in unnecessary costs.	1. Period After Opening and the appropriate symbol should also be allowed to be indicated on the label.	1. The allowance for Period After Opening will allow harmonization with the requirements of other countries and forego additional costs.
	3.1.2	1. The ingredient list should only be required to include INCI names 2. Reference is made to both categories of cosmetics – this creates confusion with respect to the scope of the draft Guideline.	1. Please only require INCI names for ingredients. 2. Please be specific in what the draft Guideline is covering in terms of its scope.	1. Requiring INCI names only will allow increased harmonization with international best practice. 2. Clarifying the scope of the draft Guideline will reduce confusion amongst stakeholders.
	3.2.4	1. Purity of materials – limits on toxic substances can be included in prohibited and restricted lists.	1. Refer to Annexure II and III of the European Union Cosmetics Regulation EC1223/2009, as amended, respectively.	1. A material will not be used or allowed for use if unacceptable levels of toxic substances are present. A COA can confirm these levels.
	3.2.5 b	1. Bacteria and fungi are not the only micro-organisms found in cosmetics.	1. Include yeasts and moulds in this section.	1. Yeasts and moulds are common contaminants in cosmetic products. Cosmetic products are highly susceptible to attack by these classes of microorganisms.
	3.2.3	1. Referring to cosmetics which are also drugs creates confusion	1. Reconsider all classes of cosmetics, to result in a	1. If a “cosmetic” has a health/medical function it is not a cosmetic.

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		and another type/class of cosmetics.	single class that performs only cosmetic functions.	
	4.4.1 – 6. – Stability data; and 7. - GMP	1. What is the difference between "special" cosmetics and "controlled" cosmetics? "Controlled" cosmetics are not previously mentioned in the Guideline. Introducing new terminology can create confusion.	1. Please clarify the difference and what the two words encompass.	1. Increased clarity will benefit the regulator and the regulated and will streamline processes.
	4.4.2.2	1. Safety Assessment – there is no indication of who can perform the assessments.	1. Mention who can carry out a safety assessment i.e. qualification. This could be a toxicologist or a suitably trained individual, but does not have to be external to the company – in-house resources can be used.	1. Companies will be clear on the requirements for safety assessments.
	Annexure 1 – Label warnings examples of warning statements	1. "Keep out of reach of children" and "For adult use only" are two different concepts so should not be given as a choice in terms of warning statements. 2. "Do not store at temperature above 120 degrees" limits the temperature warning to that level.	1. If the product is for adult use only, both statements should be given. Otherwise, for cosmetics, neither would be needed unless a safety assessment has shown there are particular risks to children if exposed. 2. The maximum temperature for suitable	1. Warning statements are important and should be provided on the packaging where it is relevant to do so. Given the increasing space limitations for labelling on packaging, it is necessary to only require what is relevant to the particular product. 2. The Guideline should be sufficiently generic to allow

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			storage may differ so should not be prescribed.	it not to be interpreted literally (where such interpretation is not warranted).
	Annexure 2 – Cosmetics claims guidance acceptable versus unacceptable label claims	1. "Active ingredient" – this wording is not usually used in the cosmetic application space.	1. This concern speaks to the principle of how cosmetics are being classified in the Guideline – any medical/health implications must result in the product not being considered a cosmetic at all.	1. Providing clarity in the scope of the Guideline and how cosmetics intend to be regulated will allow this type of confusion to be dealt with.
	Annexure 3 – The required testing parameters for cosmetics	1. "All cosmetics should be tested for heavy metals.". Which heavy metals should they be tested for? 2. Is physical testing absolutely necessary, or can a mass balance approach be used? 3. Are stability tests absolutely required as per the 14 days at 40C method referred to? Is this useful given that cosmetics may be stored much longer under undefined conditions in the home? 4. For emulsions, the stability test conditions are not provided.	1. Please provide a list of heavy metals that must be tested for. Please consider allowing a mass balance approach to be used to determine these values predictively. 2. Please consider allowing a mass balance approach to be used to determine these values predictively. 3. Please reconsider the need for stability testing as required here as the results may not be meaningful. 4. Please provide the conditions for the test.	1 – 5. Providing for mass balance approaches to be used will streamline applications and reduce costs. Providing a list of exactly what is required as well as where to find the test methods is important so that there is clarity in the regulator's expectations.

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		5. Test methods should be explicitly referenced in the Guideline.	5. Please provide at least a reference to where the test methods can be obtained.	
	Annexure 4 – Guidelines on stability testing of cosmetic products	1. Conditions for stability testing are given in this section too but are different to those given in the text above.	1. The manufacturer should be allowed to choose the test conditions given the type of product.	1. Depending on the way forward that is chosen will have an impact on costs and flexibility when it comes to stability testing – as is believed to be the intention in the draft Guideline.
	Annexure 5 – List of substances prohibited on cosmetic preparations	1. List is not updated.	1. Refer to Annexure II of the European Union Cosmetics Regulation EC1223/2009, as amended.	1. More substances are found to be CMRs and need inclusion; restrictions are ongoing.
	Annexure 6 – List of substances which cosmetic products must not contain except subject to the restrictions laid down	1. List is not updated. 2. List is difficult to read.	1. Refer to Annexure III of the European Union Cosmetics Regulation EC1223/2009, as amended. 2. Change to landscape layout.	1. Restrictions are ongoing 2. Easier to read and thus comply.
	Annexure 7 – list of colourants allowed in cosmetic products	1. List is not updated. 2. List is difficult to read.	1. Refer to Annexure IV of the European Union Cosmetics Regulation EC1223/2009, as amended. 2. Change to landscape layout.	1. Restrictions are ongoing. 2. Easier to read and thus comply.

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	Annexure 8 – List of preservatives allowed in cosmetic products	1. List is not updated. 2. List is difficult to read.	1. Refer to Annexure V of the European Union Cosmetics Regulation EC1223/2009, as amended. 2. Change to landscape layout.	1. Restrictions are ongoing. 2. Easier to read and thus comply.
	Annexure 9 – List of UV filters allowed in cosmetic products	1. List is not updated. 2. List is difficult to read.	1. Refer to Annexure VI of the European Union Cosmetics Regulation EC1223/2009, as amended. 2. Change to landscape layout.	1. Restrictions are ongoing. 2. Easier to read and thus comply.
	Annexure 10 – Symbols used on packaging/container	The "period after opening" symbol is provided in the Annexure, but the principle of its allowed use and methodologies are not referred to anywhere in the Guideline. The "date of minimum durability" symbol is provided in the Annexure, but the principle of its allowed use and methodologies are not referred to anywhere in the Guideline.	This section and requirements should be reconsidered as to what will i) be acceptable to the consumer; and ii) provide the necessary product quality and efficacy.	A PAO gives the consumer the confidence that the product will perform its function for the period indicated, as these would have been subject to tests.
	Annexure 11 – Cosmetic products standards and general guidelines	Cosmetic Product Standards and general guidelines – this includes product standards; raw material standards; standards for	A single definition for cosmetics should be used rather than separate classes which is becoming very	Please refer to the general comments above as a full review of how cosmetics are regulated – and what are

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		methods of sampling and testing. South Africa and many other countries do not use the principle of product-specific standards to regulate cosmetics on the market. As far as possible, internationally harmonized approaches are used, and ISO is followed where required. Country or Regional Economic Community-based standards that are at the product level create trade barriers. The use of such standards also creates unnecessary administrative and financial complications, without balanced reduction of risk to the consumer.	confusing, especially with the new classes/terms introduced in this draft Guideline. The use of a Standards-based approach to regulate specific cosmetics products adds to administrative and cost burden and Kenya should strongly consider moving away from this approach as the same stringent controls can be put in place on a more general basis by regulating the upstream production and testing rather than at the product level which can lead to a limit being placed on innovation.	considered cosmetics – will assist with clarifying the regulatory landscape and considering a single category for cosmetics and its associated definition. What is not a cosmetic should be regulated elsewhere.

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