ctfa
COSMETIC TOILETRY & FRAGRANCE ASSOCIATION OF SOUTH AFRICA

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Cosmetic Toiletry and Fragrance Association of South Africa's comments on the draft "Framework for the placement of cosmetics and related products into the Kenyan market"

No.	Section of the draft Framework	Description of the issue including its impact	Proposed Change/Action	Justification – an explanation why the change is necessary
2	This framework was developed for regulation of cosmetics in Kenya.	Due to the complex regulatory approach for cosmetics, it is important for the document to state clearly that PPB and KEBS are aligned in the regulatory approach being explained in the Framework. However, it is also important to make it clear that the actual document is not a legal requirement and is not mandatory. Mandatory requirements for stakeholders are found in the law, but this document is not the law.	The request alongside is partially dealt with by the provision of areas for signatures of agreement at the end of the document, thank you. However, it would be very useful to add: "Although this framework is not a legal document, the framework was developed for regulation of cosmetics in Kenya, as provided for by the respective laws." For general: The text under 7.2.2 is supported as it makes it clear that this document is not legally binding: "Regulatory	The addition of the proposed text will provide clarity that there is alignment between KEBS and PPB in the regulatory approach stated in the Framework, but that the Framework itself is not the legal document – compliance with the laws mentioned is required.

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			instruments including, standards, guidelines and where applicable procedures shall be published by the respective agencies." Please consider using this text as a framing introductory text upfront. Please also state that if there is any conflict in any law, document and/or standard that the law takes precedence.	
3.2	This framework does not cover the detailed requirements for different classes of cosmetics and related products recognized in Kenya. Applicants are required to obtain the requirements from respective agencies.	'agencies' can mean any agencies. This can cause confusion. Remove references to "related products" throughout the document as it creates confusion with regard to the scope of the framework.	Please clarify that this refers to PPB and/or KEBS, as follows: "This framework does not cover the detailed requirements for different classes of cosmetics products recognized in Kenya. Applicants are required to obtain the requirements from PPB and/or KEBS, where relevant".	Clarity will be provided as the regulatory approach is complex.
4	Definition of cosmetics	It is noted this is aligned with the EU definition. Recently, ARSO TC40 also agreed to align to the EU definition.	The existing EAS 846 Standard must be checked if this definition aligns with that given in this framework that	The alignment in the current EAS standard (if it is not already aligned) will ensure regulatory alignment in this

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		The current legally binding definition for EAC (in EAS 846) should be aligned, until such time as the ARSO standard that contains the definition is adopted. Failing to do this will result in the EAC standard having a different definition that will negate the good work of this framework document and cause regulatory confusion. i.e. in this framework, the only legal definition of cosmetics is in EAS 846.	already aligns with the agreed ARSO TC40 definition.	complex regulatory approach.
5.1.1	Risk based approach has been adopted in the classification of cosmetics and related products in Kenya. Consideration is given to potential risk on the human body and environment, ingredients, route of administration, label claims, and the target population for which the product is developed.	A link should be made between this risk-based approach (that is supported) and the new classes that are the assumed result of the risk-based approach. While CTFA prefers that there is only one class of cosmetics (e.g. current class 1 and 2 are combined, with some additional modifications)	Proposal to add text: 'Risk based approach has been adopted in the classification of cosmetics in Kenya. Consideration is given to potential risk on the human body and environment, ingredients, route of administration, label claims, and the target population for which the product is developed. This has resulted in the categorisation of	Wording changes will increase clarity. Having a single class will simplify the regulatory approach. PPB can then by Notice determine what it needs to further regulate.

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		and one regulator, the proposal alongside would be supported until such time as there can be a "one class-one regulator" approach adopted.	cosmetics into class 1 and class 2 cosmetics. <u>Please make contact should you wish to consider a further proposal regarding how the two current classes can be combined, with some additional modifications.</u>	
5.2 and 6 and 7	For the purpose of regulation, cosmetics and related products shall be classified as follows	The use of the word "regulation" implies that what is laid out in this document is the law and this is not the case. The document is an explanatory document including an agreement between PPB and KEBS. The text outlining the classes can be confusing. For example, 7.1.3 can be understood to mean that 7.1.2 is a list of Class 2 cosmetics. For example, 7.1.4 Cosmetic products that fall under Class 2 shall be regulated by the Kenya	The following wording should be incorporated in the document to provide ultimate clarity. As provided for in law, both PPB and KEBS have the mandate to regulate cosmetics. Different classes of cosmetics will be regulated differently according to the risk-based approach above that is according to their criteria given. PPB will regulate the listed Class 1 cosmetics only, while KEBS will regulate all Class 1 and Class 2 cosmetics.	Increased regulatory certainty will be provided by including the proposal.

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		Bureau of Standards. Applicants intending to market this class of products are required to comply with the applicable standards and requirements found at www.kebs.org	This is a simplified wording that provides the necessary clarity. The previous Class 1 cosmetics (now Section 6) will only be regulated by PPB and are no longer considered cosmetics at all. 7.1.4 should be deleted as it is in conflict with 7.1.3; etc. (where it is stated that some class 2 products are not regulated by KEBS).	
7.1.3	All other Cosmetics and related products that fall under Class 2)) but are not listed above shall be regulated by the Kenya Bureau of Standards. These include the products listed below. Applicants intending to market this class of products are required to comply with the applicable standards and requirements found at www.kebs.org	This section is unclear. This section should refer to special cosmetics and not just cosmetics. The text should state that the list is "not limited to".	All special cosmetics that fall under Class 2 but are not listed above shall be regulated by the Kenya Bureau of Standards. These include but are not limited to the products listed below. Applicants intending to market this class of products are required to comply with the applicable standards and requirements found at www.kebs.org	
7.3.1 and 7.3.2	Under this framework, a manufacturer is responsible for post market surveillance. He is to collect and evaluate experience gained from products that have been placed on the Kenyan	This is different in different countries which makes it difficult to	In the interests of harmonisation across Africa, including for the purposes of the AfCFTA as well as mutual	

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	market, and to identify the need to take any action. Any such actions shall be shared with the responsible agency. In exceptional cases the responsibility for post market surveillance shall lie with the distributer/importer/wholesaler, responsible for the placement of a product in the Kenyan market.	harmonise approaches across Africa.	recognition and conformity assessment, it is recommended that this approach be reconsidered and that either is acceptable.	
7.3.6	Handling of market complaints, Corrective and Preventive Actions (CAPA) follow-up, recalling/withdrawing, reshipment, destruction and seizure.	As this is a part of 7.3.5, delete the numbering "7.3.6". These requirements must also be stated in documents provided for in the law.	As this is a part of 7.3.5, delete the numbering "7.3.6".	Typographic proposal.
8.1.1	There will be a one year transition period from the date of signing this framework to comply with the requirements of this framework.	This is not a legal document in itself, but merely provides information on how different cosmetics are to be regulated. Will existing authorisations need to be redone in cases where the regulator has changed?	It should rather state that once signed, the PPB and KEBS will immediately be available for stakeholders to undertake any necessary processes required by the law. Stakeholders however have one year to comply with the law.	Stakeholders need active regulators to engage with to be able to comply within one year.
8.1.2	This framework may be amended or supplemented at any time by agreement between the Pharmacy and Poisons Board and the Kenya Bureau of Standards.	Supported, but please can any proposed amendments be engaged on in draft format with	Please list CTFA as a stakeholder and please provide proposed policy; regulatory; and technical changes well in advance so	

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		national and international stakeholders. Sufficient time must be given for input and engagement.	that there can be sufficient review; comment; and engagement. Please note the WTO processes that also need to be followed if there is going to be regulatory change.	

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