FEEDBACK TEMPLATE TO THE KEBS/PPB FRAMEWORK

Section of the Framework	Issue – *Describe what is wrong with the section*	Proposal – *State what you would like done e.g. delete the section, amend or replace*	Justification – *Give reason why the change is needed and how it will benefit the industry*
1.2 Kenya Bureau of Standards	"Conformity assessment services carried out by KEBS include inspection (import and export), quality assurance (product certification), market surveillance" Comments: • These activities, amongst others are relevant and supported activities that KEBS can be undertaken for all 'cosmetics'. • KEBS has the capacity to undertake them for "cosmetics". • There is no need for two-regulator approach for the regulation of "cosmetics", as defined.	• Only KEBS should regulate "cosmetics" due to their low risk profile. • However, PPB will have a role through in-market compliance monitoring and enforcement – if a product does not appear to be a cosmetic based on its ingredients and/or claim then it can be addressed by PPB if it is considered to be a drug/medicine; etc.	• There are sufficient standards in place that – taken together with the mandatory nature of standards in Kenya – the country can be assured of more than adequate regulation by KEBS. • Compliance monitoring and enforcement activities by KEBS and PPB need to ensure that "cosmetics" (as defined) and the responsible persons are compliant with the requirements. PPB's role. • The single type of product called "cosmetics" will be adequately regulated.
3.2 Scope	"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."	• "This framework does not cover the detailed requirements for different cosmetics as recognized in Kenya. Applicants are required to obtain the requirements from KEBS."	• Consistent wording should be used throughout the document, to achieve regulatory certainty. • There are sufficient standards in place that – taken together with the mandatory nature of standards in Kenya – the country can be assured of more than adequate regulation.

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	Comments: • "and related products" has not been deleted while it has been in other parts of the document. • Different classes of cosmetics creates uncertainty and challenges for implementation, especially if there is no rational risk- and/or science-related basis for the classification system and regulation by different authorities. • These activities, amongst others are relevant and supported activities that KEBS can be undertaken for all 'cosmetics'. • KEBS has the capacity to undertake them for "cosmetics". • There is no need for two-regulator approach for the regulation of "cosmetics", as defined.	• Only KEBS should regulate "cosmetics" due to their low risk profile. • However, PPB will have a role through in-market compliance monitoring and enforcement – if a product does not appear to be a cosmetic based on its ingredients and/or claim then it can be addressed by PPB if it is considered to be a drug/medicine; etc.	• Compliance monitoring and enforcement activities need to ensure that "cosmetics" (as defined) and the responsible persons are compliant with the requirements. • The single type of product called "cosmetics" will be adequately regulated.
3.3 Scope	"The framework does not cover implants, injectables, inhalers, enteral and nutricosmetics". Comments: • It is supported that these are not cosmetics.	• "The framework does not cover implants, injectables, inhalers, enteral and anything else not considered a "cosmetic", as defined in EAS 846.	• The proposal creates clarity and ensures that the scope of regulation and the document can be appropriately implemented.

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	• The term "nutricosmetics" should not be used as it creates confusion.		
4 Definition of terms – cosmetic product	"any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours." Comment: • The definition is supported. • Some of the listed substances that PPB wants to regulate form part of this definition. Please refer to comments below.	• Only KEBS should regulate "cosmetics" due to their low risk profile. • However, PPB will have a role through in-market compliance monitoring and enforcement – if a product does not appear to be a cosmetic based on its ingredients and/or claim then it can be addressed by PPB if it is considered to be a drug/medicine; etc.	• There are sufficient standards in place that – taken together with the mandatory nature of standards in Kenya – the country can be assured of more than adequate regulation by KEBS. • Compliance monitoring and enforcement activities by KEBS and PPB need to ensure that "cosmetics" (as defined) and the responsible persons are compliant with the requirements. PPB's role. • The single type of product called "cosmetics" will be adequately regulated.
5.2 Categories and placement on the market	• "For the purpose of regulation, cosmetics shall be categorized as follows:". Comments: • Different classes of cosmetics creates uncertainty and challenges for implementation, especially if	• Only KEBS should regulate the single class of products called "cosmetics", due to their low risk profile. • However, PPB will have a role through in-market compliance monitoring and enforcement – if a product does not appear to be a	• There are sufficient standards in place that – taken together with the mandatory nature of standards in Kenya – the country can be assured of more than adequate regulation by KEBS. • Compliance monitoring and enforcement activities by KEBS

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	there is no rational risk- and/or science-related basis for the classification system and regulation by different authorities. • These activities, amongst others are relevant and supported activities that KEBS can be undertaken for all 'cosmetics'. • The wording does not provide sufficient legal or other justification for the need to have more than one type of "cosmetics" and more than a single regulator. • It is not understood why this "multiple class, multiple regulator" approach to the regulation of cosmetics is required, given the low risk profile of the products.	cosmetic based on its ingredients and/or claim then it can be addressed by PPB if it is considered to be a drug/medicine; etc.	and PPB need to ensure that "cosmetics" (as defined) and the responsible persons are compliant with the requirements. PPB's role. • The single type of product called "cosmetics" will be adequately regulated.
5.2.1 – 5.2.3 Special cosmetic products	"Products that, while making no explicit medical claim, contain ingredients/composition or are marketed with claims/promises to deliver for preventing or interfering with normal operation of a physiological function whether permanently temporarily or whether by way of terminating, reducing, postponing or increasing or accelerating operation of the	• There should be a single type of product called "cosmetics" that meet the definition and do not have therapeutic/medical claims/ingredients above cosmetic thresholds, or are otherwise regulated. • The following product in list 5.2.3 can be considered cosmetics due to the low risk	• "Cosmetics" will be those products that meet the definition of "cosmetics" and do not have medical/therapeutic claims and ingredients above cosmetic thresholds, or are otherwise regulated. • For example: o Anti-ageing cosmetics could rather be: "reduce visible signs of ageing".

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	functions in human beings fall under this category." Comment: • The category "Special cosmetics" should not exist as a category, as most of those products included in the list given in 5.2.3 do not meet the definition of "cosmetics". • Suncare products are the exception in the list - they meet the definition of "cosmetics" and should not be included in the list of "special cosmetics". • What is the word "composition" referring to if not ingredients?	and meeting the definition of "cosmetics": ○ "Sunscreens and sun protection products". • The other products in the list are not considered cosmetics due to the claim being made:	○ Anti-wrinkle cosmetics could rather be: "reduce visible signs of ageing". ○ Anti-dandruff cosmetics could rather be: "reduction of visible scalp flakes". ○ Anti-inflammatory products would never be cosmetics. ○ Hair growth promoting/restoration products could rather be: "assists with the promotion of hair growth". ○ Anti-hair loss products could rather be "assists with slowing down hair loss". ○ Aromatherapy substances would never be cosmetics, but could be ingredients at allowed limits for cosmetics. ○ Hydroxy Acids: Alpha Hydroxy Acids (AHAs), Beta Hydroxy Acids (BHAs), Poly Hydroxy Acids (PHAs) can be considered on a case-by-case basis.

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			• In this way there is no over-regulation, while risk and consumer expectations are being managed appropriately.
6.1 – 6.4 Products with medical/therapeutic claims	"These are products or any substances or mixtures intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity containing medical/therapeutic claims or containing pharmaceutical ingredients." Comments: • The words "containing medical/therapeutic claims or containing pharmaceutical ingredients" makes these product drugs/medicines (etc.) and not cosmetics, so the approach is supported. • However, in the list in 6.3, "Products for clearing dark circles around the eyes" should remain a "cosmetic" unless there are medical/therapeutic claims made and medical ingredients used above cosmetic thresholds.	• For "Products for clearing dark circles around the eyes": there is no medical/therapeutic claim applicable and as long as ingredients are used within cosmetic-related restrictions there is no reason why such cannot be considered a cosmetic.	• A product meeting the definition of "cosmetic" should be treated as such by a single regulator (KEBS).

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8. Transition period	"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." Comment: • This short transition period may cause unnecessary pressures on the value chain. "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." Comment: • The legal status of this Framework versus the law requires clarification.	• This period should be 2 - 3 years given the long value chain that is involved in these products. • Stakeholder participation is recommended before any changes are brought into effect, so that they can be discussed and industry buy-in can be obtained.	An appropriate transitional period will allow the necessary regulatory changes to take effect in an ordered manner, without shocking the market or causing unnecessary pressures on already stressed value chains.

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