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Cosmetic, Toiletry & Fragrance Association of South Africa's comments on the "Management Response" version of the Zimbabwe Draft Cosmetic Statutory Instrument

Clause	CTFA comment	CTFA proposal
Arrangement of Sections	9. Authorised person • The authorised person may not be the responsible person. • 'authorised person' is not defined, but is used along with 'responsible person'.	9. Responsible person • CTFA recommends the use of one word. • Proposed text can be found in the relevant section below.
	29. Variation, amendment and cancellation of permits • 'revoke' and 'cancel' are used interchangeably in the draft regulations.	29. Variation, amendment and revocation of permits • CTFA recommends the use of one word. Changes have been proposed in the Regulations below.
2. Interpretation	• "national standard": these words are not used, so they do not need to be defined.	• Delete.
	• "new cosmetic": it is noted that the regulation focuses on 'new cosmetics'. How will existing cosmetic products that may not align with the requirements and may be causing problems in the market, be handled? This is an important point for clarity of scope - will the regulations only apply to new cosmetics, as defined? Is there a phase-out being considered for cosmetics that do not meet the requirements of these regulations?	• Please provide clarity of scope and intention.
	• "shelf-life": how is 'shelf-life' different to date of minimum durability?	• CTFA proposes that only 'date of minimum durability' that includes the need to use PAO where required, is used in the regulations to forego confusion. (Date of minimum durability (best before) (when this is less than 30 months)

	• If this definition is to be retained, it is not clear why the Authority would affix the label? This would be the responsible person's responsibility.	and Period After Opening (if more than 30 months)). Delete this definition and refer to proposals below. • If the definition is retained, replace "Authority" with "responsible person".
	• "undesirable events": EU Regulation 1223/2009 only refers to 'undesirable effects'.	• Please delete this as it is the same definition given below for 'undesirable effects'. The proposed changed is made throughout the regulation.
	• "serious undesirable events": EU Regulation 1223/2009 only refers to 'serious undesirable effects'.	• Please delete this as it is the same definition given below for 'serious undesirable effects'. The proposed changed is made throughout the regulation.
	• "withdrawal": this does not make sense, as a withdrawal would only take place if something was already on the market. • Please note that the word is not used in the regulation, only on Form C12.	• Please clarify or delete. "Recall" covers this requirement. • The word can be deleted.
4. Exemptions	• (1)(b): although Regulation 3 provides that the country is the limit, additional clarity here would be appreciated.	• "that is exported from Zimbabwe and is not intended for commercial supply in Zimbabwe. ".
	• (2): '(e)' can be stated specifically. • This provision is too broad. Regulated entities must be made aware upfront of what needs to be complied with. This is good regulatory practise. If 'necessary or desirable' conditions are to be set, at least the range must be given in the regulations.	• "Where a cosmetic is imported solely for re-export as provided in subsection (1)(e), the responsible person shall make an application for exemption to the Authority.". Please also consider this principle for 12(3); 25; etc.. • Please provide the range of conditions that may be required or desired. Please also consider this for 12(3); 25; etc..
5. Particulars	• This provision is too broad. Regulated entities must be made aware upfront of what needs to be complied with. This is good regulatory practise.	• If further information or particulars are aligned to the contents of the Form, the Form can be referred to here. For example: 'with further information or particulars as required in Form xxx.".
9. Authorised person	• As proposed above, rather use responsible person.	• Change all instances of "authorised person" to "responsible person". • "The responsible person shall ensure compliance of the cosmetics made available on the market, in terms of these Regulations.".

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10. Safety	• (1): as proposed above, rather use responsible person.	• Change all instances of "authorised person" to "responsible person". • "The responsible person shall ensure compliance of the cosmetics made available on the market, in terms of these Regulations.". • Please also make these changes to 11(1), (3).
	• (2): missing text.	• Add "on the market". • "Any person responsible for placing a Category 2 cosmetic on the market shall ensure that the cosmetic has undergone a safety assessment of the finished product and its ingredients before being placed on the market. ".
12. Duty to notify Authority of supply of cosmetics	• (4)(a): add text for clarity. • 4(b) and (c): move the placement of the word "and".	• Proposal for (4): "A notification for the purposes of subsection (1) shall be submitted to the Authority in **FORM C3** and shall be accompanied by — such particulars, information, documents and samples of the cosmetic as the Authority may require as stipulated on FORM C3; (b) where required by the Authority, a declaration by the applicant verifying any information contained in or related to the notification; (c) the appropriate fee specified in the **FIRST SCHEDULE**; and (d) in the case of Category 2 cosmetics, the notification shall be accompanied by a safety assessment report in terms of Section 10 and a Product Information File in terms of Section 11. ".
	• (5): "either before or after the notification of supply of cosmetic"- this text is not required as a notification is required prior to the placing of a cosmetic on the market.	• (5): "Every applicant shall, without delay, inform the Authority- ".
	• (6)(c): It is arguable whether this would be considered a cosmetic if it is being used by patients.	• It is proposed to delete (c), as such as substances would be covered as a medicine in other legislation. Please confirm the intention.

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		• (6)(c): "a cosmetic that is manufactured by or in accordance with the specifications of a medical practitioner, and supplied solely for the use of patients.".
16. Labelling of cosmetics	• (2): taking proposals made above into account as well as some inconsistencies and duplication, the text alongside is proposed to replace the whole of 16(2).	• (2): "Every primary and secondary container of any cosmetic product shall be affixed with a label bearing the following particulars pertaining to the contents of such container in clearly legible- and indelible letters in English- (a) name of the cosmetic; ○ Product Description; ○ instructions of use; ○ nominal content at the time of packaging given by weight or volume, in accordance with the Metrology Act (Chapter 14:06); ○ name and address of the manufacturer, including country of origin; ○ date of minimum durability; ○ list of ingredients according to INCI nomenclature, listed in descending order of concentration in the finished product; ○ batch number; and ○ precautions and warnings where applicable.".
	• (3)(c): only date of minimum durability should be required. Please refer to the comment above.	• (c): "date of minimum durability.".
20. List of ingredients, and 21. Form of ingredients list	• In order to align with the EU and remove duplication and some confusion, it is proposed that the whole of 20 and 21 be replaced with the text alongside.	• The text of the FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972 (ACT NO. 54 OF 1972) REGULATIONS RELATING TO THE LABELLING, ADVERTISING, AND COMPOSITION OF COSMETICS (South African Draft), is proposed - where relevant (for example Section 10). • Please note that the following are supported as additional to the draft South African regulations:

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		• references to a range of products such as in subsection (5) that it be replaced with 'product variants' (already defined); • 'incidental ingredient' is replaced with 'trace amount' (already defined); and • only INCI names are allowed.
22. Composition of cosmetics	• CTFA acknowledges and appreciates the alignment to the EU. However, it will be more efficient from a regulatory point of view NOT to list the specific substances in the Annexes, as the list changes from time-to-time. Rather refer to the list name so it can be reviewed by those being regulated. In this way the Zimbabwean legislation will remain updated, affording the consumer the highest level of protection and the regulator will not have to continually update the legislation text.	• Make direct reference to the EU lists so they can be reviewed by those being regulated.
23. Control of imports and exports	• (3): "shall have in place a system of notification" – it is not clear what is being required.	• Please clarify the requirement.
24. Application for the issue of import or export permit	• (2)(c): "the Global Cosmetic Nomenclature System GCNS" – it is not clear what this is.	• Please clarify – is this supposed to be referring to INCI?
	• (2)(g), and (3)(d): "the Zimbabwean authorization number"- it is not clear what this is.	• Please clarify – is this the business registration number? If so, what if the business is not registered in Zimbabwe, but in another country?
	• (4): add text for clarification.	• (4): "Every application for an import permit for Category 2 cosmetics shall be accompanied by a copy of the Product Information File in terms of Section 11 of these Regulations.".
28. Verification of consignments	• Remove reference to export, as verifications and fess should not be required for export.	• "Every person who is issued with an import permit in terms of Section 25 shall, on the importation of such cosmetic pay a consignment verification fee prescribed in the …".

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29. Variation, amendment and revocation of permits	• (1)(b): "as he or she deems fit" is very broad.	• Please include that reasons will be provided.
32. Manufacturing premises to be licensed	• (3): The person that is expected must be liable to pay a fee where this is a mandatory inspection by the Authority.	• Delete reference to a fee being liable: "The Authority may conduct an inspection of any premises that manufacture cosmetics for which approval is sought or otherwise.".
37. Undesirable effects	• Please see the proposed text alongside that has numerous changes aligned to the comments above.	(1) "In the event of undesirable and serious undesirable effects, the responsible person must have a process in place to handle them. (2) Where consumers report undesirable and serious undesirable effects to the responsible person, the responsible person must without delay record the event and investigate and notify the Authority. (3) The undesirable and serious undesirable effects must be recorded in the Product Information File where it has taken place for Category 2 cosmetics. (4) The responsible person must conduct regular reviews of the reported undesirable and serious undesirable effects, in order to detect trends and take action, as needed.".
40. Offences and penalties	• There are already fines provided in the relevant sections of the text. Does this provision apply to all others?	• "Any person who contravenes or fails to comply with any provision of these regulations where there is not already a penalty stipulated, shall be guilty of an offence and liable on conviction to a fine not exceeding level twelve or to imprisonment for a period not exceeding ten years or to both such fine and such imprisonment.".
Annexes	• Information requested that includes proprietary information such as quantity and proportion of ingredients is not supported.	• Please remove these requirements.

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