January 6, 2016

Mr. Qi Liubin
China Food and Drug Administration
Department of Drug and Cosmetic Registration
Beijing
People Republic of China

hzpc@cfda.gov.cn

RE: Comments on Draft CFDA "Cosmetics Safety Risk Assessment Guidelines"

Dear Sirs,

Warm Greetings from the ASEAN Cosmetic Association!

We wish to thank you in advance for allowing us to participate and contribute to the ongoing development and strengthening of the cosmetic regulatory framework in China to ensure consumer protection. Our association, strong of its 900 members spanning over ASEAN, has been continuously collaborating with governments and industry partners in regulation development in ASEAN and Asia to help achieve the ideal state of regulatory system that will benefit all stakeholders, primarily the Asian consumers. ACA is pleased to offer any support to CFDA in your effort to strengthen the cosmetic legislation in China.

ACA has been the industry stakeholder collaborating with the ASEAN Regulatory Authorities (ASEAN Cosmetic Committee or ACC) for developing the ASEAN Cosmetics Safety Assessment Guidelines, the ASEAN Cosmetics Safety Assessment Report and the training modules for implementation.

ACA welcomes the draft CFDA Guidelines as an important step. Safety assessment is a key element of safety legislation. In many aspects the Draft Guidelines are compatible with International practices and in particular with the ASEAN Guidelines. In particular the need for a risk based approach reflecting sound science.

Some of the points we would like to raise concern:

1. In assessing the safety of ingredients, expand the scope of the data to include not only "toxicology studies, clinical research, undesirable effects monitoring and human epidemiological studies" but also data derived from alternative to animal tests or *in silico* data, and give credence to the weight of evidence and TTC;
2. We are concerned that the term "misuse" might be beyond the scope of the risk assessment. Reference to "reasonably foreseeable use" would be more appropriate, as there always might be non-foreseeable misuses which the safety assessor cannot evaluate;
3. Microbiology preservation: ISO TC 217 Cosmetics has issued numerous standards on the microbiology of cosmetic products. A reference to the Guidance document ISO 29621 "Guidelines for the risk assessment and identification of low risk products" as well as ISO 11930 "Evaluation of the antimicrobial protection" could be included;
4. Fragrances: like in ASEAN, we think that reference to the IFRA Code of Practice is sufficient. There is no need for the semi quantitative analysis;
5. For those ingredients that have been evaluated by the CIR, the SCCS, IFRA, WHO, FAO, OECD, etc. the conclusions should be leveraged without further need for safety assessment;
6. We are also concerned with the length of time the results need to be kept, 10 years after the last batch has been produced is a long time for fast moving consumer goods. It is usually considered that 5 years is a sufficient timeframe;

ACA has developed training modules for the SMEs and we stand ready to share these.

Thank you very much for the opportunity to share our position and comments. We would highly appreciate if CFDA continues to maintain the open and regular dialogues with the Cosmetic Associations. By continuing involving the industry Associations into the discussion and development of the regulation, it helps the industry to understand and find ways to fully comply with the regulation.

Sincerely,

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Cc: Mrs. Ketmanee Lerkticha, ASEAN Cosmetic Association Chairman of the Board;
Dr. Preecha-Korn Suvanaphen, President ASEAN Cosmetic Association;