

# JAPAN COSMETIC INDUSTRY ASSOCIATION

8 February 2019

To EU-TBT Enquiry Point  
European Commission

Re: Draft Commission Regulation Amendment of Regulation (EC) No 1272/2008 and Regulation (EU) 2018/669

Dear Sirs/Madams,

On behalf of Japan Cosmetic Industry Association representing interests of cosmetic industries of Japan, I would like to make the following comments regarding the proposed regulation posted on WTO TBT Notification G/TBT/N/EU/629 dated 12 December 2018.

JCIA was established in 1959 and currently represents interests of cosmetic industry of Japan, consisting of over 1,200 members including most major global cosmetic companies. JCIA has paid great attention to analyze implication of regulatory schemes to international trade of cosmetics closely collaborating with Japanese governments to facilitate international trade of cosmetic products.

We concern that there are no sound scientific grounds justifying the proposed classification of the powder containing 1% and over of 10µm or less TiO<sub>2</sub> as carcinogenicity 2 (inhalation).

Our comments are as follows:

We believe that there is no evidence showing carcinogenic potential of TiO<sub>2</sub> on human from following reasons. Among epidemiological studies including epidemiological cohort studies and population based case control studies, none of them was identified to prove the clear correlation between the occupational exposure to TiO<sub>2</sub> and carcinogenicity in the respiratory organ. TiO<sub>2</sub> has been used in cosmetic products and over-the-counter drugs for more than 90 years. However the causal relation of the carcinogenicity associated with TiO<sub>2</sub> has not been reported since TiO<sub>2</sub> has been placed in the market.

Under the circumstances, France submitted a proposal for CLH classification of TiO<sub>2</sub> as carcinogen to ECHA based on the conclusion of IARC. However, it has been attracting social attention whether the evaluation method used in the study report cited in IARC

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Monographs is consistent with OECD test guideline. It is suggested that that the lung epithelial cancer observed in the study report could be due to secondary effect by overloaded powder, not because of its own hazard of  $\text{TiO}_2$ , in IARC Monographs Volume 93. RAC opinion announced in June 2017 also suggests that the lung epithelial cancer observed in the study report should be due to secondary effect by overloaded powder, not because of an assumption that  $\text{TiO}_2$  has its own hazard. It clearly supports the conclusion of IARC Monographs Volume 93. In this regards, we believe that  $\text{TiO}_2$  has been demonstrated to hold no hazard of its own.

In addition,  $\text{TiO}_2$  subject to the new regulation is not clearly defined. The size of  $\text{TiO}_2$  measured by certain situation is highly dependent on its physical state in matrices. Thus, it is essential to develop a unified precise pretreatment protocol before measuring the size of particles. It is easily imagined that there will be practical difficulties in applying this proposal. Therefore, the reliable method is to be established and be acknowledged throughout the supply chain with respect to defining specification of objected  $\text{TiO}_2$ . And a rationale why a cut off value for size of  $\text{TiO}_2$  is set at 10  $\mu\text{m}$  or less should be explained from the point of risk assessment.

We highly appreciate the opportunity to present our views on the proposed regulation and sincerely hope taking into consideration those comments.

Respectfully yours,



Japan Cosmetic Industry Association