

Messrs. European Commission,

We are grateful for the opportunity to submit our opinion toward WHO/TBT notification.

We are Carbon Black Association of Japan.

For the following reasons, we deem it is not appropriate to be classified as Titanium dioxide as a category "2" carcinogen.

- (1) As a result of overload tests conducted on rats, the carcinogenicity of Titanium dioxide was evaluated by the IARC as "2B".

All other materials, including Carbon black, Titanium dioxide, Silica and Talc, were likewise evaluated as "2B" from the data indicating the incidence of "carcinomatous degeneration" in overload tests conducted on rats.

However, the long-term data collected from workers in plants does not provide any evidence that causes concern over the carcinogenicity of Carbon black. The IARC also made a similar decision in this regard.

In other words, the evidence of carcinogenicity provided by the IARC is specific to species of rats, and therefore should not be applied to humans.

- (2) Carbon black, Titanium dioxide, Silica, Talc, etc. are materials that are utilized widely and effectively in many places of human activity.

Furthermore, there are very few alternative materials. Within this context, labeling should not be used for the materials that have no clear evidence of carcinogenicity.

- (3) Workers in Carbon black plants have been tested worldwide, however, many data indicating "negative" for carcinogenicity has not been correctly reflected.

- (4) It is appropriate to control the materials based on the allowable concentrations (already adopted) for safe handling, instead of labeling the materials based on the overload conditions that could never occur in the natural world or human society.

- (5) It is obvious that Titanium dioxide as well as Carbon black is PSLT (dust).

Regulating such dust under the CLP regulations runs counter to the purpose of the CLP regulations.

A process to calculate and control appropriate occupational exposure levels for each occupation should be created.

(reference)

CLP regulations: Regulates substances that have intrinsic hazardous properties.

Since Titanium dioxide as well as Carbon black does not have intrinsic hazardous properties (factors that induce cancer), the CLP regulations should not be used to regulate them.

Carbon Black Association of Japan



