**Technical justification of the Position of SCHP ČR, ANP ČR and ČSAF on the RAC Opinion suggesting harmonized classification and labelling of titanium dioxide (TiO2 ) at EU level.**

The RAC Opinion suggests the classification of titanium dioxide as Category 2 – Suspected Carcinogen by inhalation. The effect seen with TiO2 at extremely high concentrations is not unique to TiO2 but it is characteristic for all poorly soluble substances with low toxicity - "inert dust". RAC acknowledges that the carcinogenicity profile described for TiO2  is not only exclusively characteristic for TiO2  but applies to a group of chemicals with similar toxicity profile addressed as "poorly soluble low toxicity particle.“ The RAC Opinion concentrates on the lung overload state due to the long- term effect of extremely high TiO2 dust concentrations, i.e. under conditions way above the maximum physically tolerated dust dose. RAC does not consider solving the health concern via the sufficient dust control mechanisms offered by the existing EU legislation and Recommended Exposure Limits (RELs).

Tumors in rats develop only under the conditions of extreme and long-term lung overload with dust, when the clearing function of the pulmonary cells stops and inert dust accumulate in lungs even for several years. It was accepted by all experts and participating parties that any inert material in the form of dust may cause tumors in rat lungs under long-term overload conditions, which is however purely physical effect of the dust particles. Inhalation symptoms of TiO2  at extremely high concentrations (long-term lung overload at 25 times higher TiO2 dust concentrations than the legally authorized limits) are only a dust particle effect / physical effect that is not specific to a particular substance.

The reliability of Heinrich 1995 and Lee 1995 study in rats used as an evidence in the French TiO2 classification proposal are very low (R3 and R2 ratings in the context of the ECHA and OECD guidelines). Professional evaluation and determination of reliability of the studies is required before they would be used for any regulatory purpose.

In our opinion, there is no reason to classify TiO2 as well as we find no benefits of the classification for the environment and consumers and workers safety. The occupational workplace dust exposure limits are sufficiently governed by Member States' regulations and industrial practices today. They are the correct and most adequate way of protecting workers and consumers against extreme dust concentrations and long-term exposure, leading to lung overload in consequence. Epidemiology studies of more than 24,000 workers demonstrate no correlation between a long-term exposure to TiO2 and lung tumors. According to the data from the industry, none of the present uses of TiO2 have ever resulted in significant adverse health effects or lung carcinoma. In addition, there is a complete alternative database of TiO2 interaction with lungs, since TiO2 has been used as a control sample of inert dust in inhalation toxicology studies for decades, precisely because of its total inertness to the organism.

 The classification of TiO2 as cat. 2 – Suspected carcinogen by inhalation would have broad public policies and regulatory impacts, going far beyond the specific substance. It would imply a precedent for more than 300 other inert substances (e.g. iron oxides) and then again for all existing substances. We share the justified concerns of the industries and consumers about the stigmatisation of products, impact on EU wider policy objectives , notably the Circular economy, competitiveness, reputation and potential loss of the market (10 to 15%), with the increased costs for downstream users and consumers on the other end.

We support the TDMA proposal to set up a Working Group of the Member States, ECHA, the European Commission, NGOs and industry experts, which would suggest an appropriate mechanism for any regulation of PSLTs including their regulation through OELs and recommend updates of the existing classification process.

In our opinion, the CLP Regulation is not a suitable regulatory tool to address issues related to inert substances, especially when the classification efforts raise important questions about the purpose of the valid legislation in the context of classification of the actually chemically active substances 'intrinsic toxicity'.

The protection of workers at their workplace and the protection against any excessive dust concentrations are now sufficiently warranted through the Member’s State regulations and industrial practices.

**Thus, the proposed classification of TiO2 should not be translated into Annex VI.**

An immediate classification of TiO2 would have broad regulatory implications going far beyond the CLP Regulation in the downstream legislation. Moreover, it would set a precedent applicable to a broad range of PSLT substances as highlighted in the RAC Opinion, and additionally, to all existing substances. We agree with the concerns about the proposed classification raised by the European Commission and several Member States. We support the call by the Member States that due to numerous issues, devoting more time to the submittal, and further discussions of all participating parties should take place before taking any decision. We also support the intention expressed by competent authorities of several Member States to set up a PSLT working group to determine the appropriate risk management options and postpone further regulatory measures before then. In this connection, we welcome the UK proposal that the Commission establishes a ‘task and finish’ sub-group of CARACAL to take forward the discussion that has already started.

We believe that the above mentioned issues should be considered as part of, or parallel to the 2018 CoRAP TiO2  review, especially the appropriateness of the existing workplace occupational safety legislation that simply, unambiguously and unprecedentedly covers the **identified problem** of the long-term lung overload by TiO2 and/or any other inert dust, and already consistently prevents such an exposure of high dust concentrations via monitoring and control mechanisms (RELs).