BDI Bundesverband der Deutschen Industrie e.V.
VERBAND DER CHEMISCHEN INDUSTRIE e.V. WIR GESTALTEN ZUKUNFT. VCI
Verband der deutschen Lack- und Druckfarbenindustrie e.V.
Verband der Mineralfarben-industrie e. V.

Comments

regarding the discussion about the
"**Classification of TiO_2 and mixtures containing TiO_2**"
at the meeting of CARACAL,
16 November 2017

We welcome the opportunity to provide comments following the discussion that took place during the 25th meeting of Competent Authorities for REACH and CLP (CARACAL) on 16 November 2017 under agenda point 17 ('Classification of TiO2 and mixtures containing TiO2').

In our view, the discussion showed that there are serious concerns regarding the applicability of the CLP regulation to dust effects and that a more in-depth discussion is necessary. This fundamental aspect is not addressed in the Commission´s working document (Doc. CA/90/2017), however we believe that the CARACAL members should have the possibility of a full debate. Therefore, we would like to comment not only on the questions about adaptations and derogations raised by the Commission but to address also the underlying fundamental question of applicability.

Fundamental aspects discussed at CARACAL:

- **Non substance-specific dust effects**

In the working document, the Commission correctly points out that the **RAC does not assume an "intrinsic" toxicity of titanium dioxide** and that its recommendation is based on the "poorly soluble" property and the resulting particle effects. ("*The mode of action cannot be considered "intrinsic toxicity" in a classical sense but is characterized as particle toxicity*."). We welcome this clarification.

- **Applicability of the CLP regulation to dust effects**

Unfortunately, the Commission subsequently neglected to draw the corresponding conclusions or at least to cast a doubt on whether the CLP regulation is even applicable regarding such particle effects. The recommendation made by the RAC to extend the scope of applicability of the CLP regulation by using substance-unspecific properties for the classification would create a **precedent for the classification of all poorly soluble substances** in powder form. Such approach raises considerable regulatory, legal, economical and health policy concerns, which are not reflected in the working document.

On the contrary, the working paper indicates that the Commission is willing to think about adaptations or exceptions without prior clarification of this fundamental question ("*As correctly remarked by RAC, the CLP regulation does not exclude a health hazard classification triggered by physico-chemical characteristics of a chemical, and the Commission has **no reasons to question** the correctness of the proposed classification of TiO_2 if inhaled as small particles*.").

The CLH-proposal and the recommendation by the RAC have already given rise to **significant uncertainties in the affected industries and their customers**. We therefore recommend that the open questions are clarified by an **impact assessment** and a statement by the European Commission **Legal Service**. A mere continuation of the CLP process would otherwise substantially increase the uncertainties, with negative effects for the industry throughout Europe.

- **Scientific basis for the classification**

It is our opinion that the existing **scientific data do not justify a classification** of titanium dioxide: There is an ongoing controversial debate about how relevant studies with high dust concentrations on rats are for humans. In particular, there is a great uncertainty regarding the extent to which knowledge gained from inhalation tests with rats can even be transferred to humans at all. The recommendation made by the RAC is fundamentally based on a single study with rats that goes back 20 years and is clearly not conform with the guidelines. The RAC did not take the numerous epidemiological studies into account which showed that under real-life conditions there is no connection between the exposure to titanium dioxide and the risk of developing cancer.

Unfortunately, the working paper uncritically accepts the recommendation made by the RAC without pointing out the open scientific questions and the weaknesses of the study the recommendation is based on.

<u>Questions raised by the European Commission:</u>

- **Question 1:** *Do CARACAL members and observers consider that the proposed classification of TiO_2 can be **translated directly into Annex VI**, or, taking into account the scientific evidence, is there a **possibility for adaptations** (e.g. through further footnotes to differentiate between particles that can be inhaled and larger particles/massive forms of TiO_2)*?

The classification of titanium dioxide under the CLP regulation is not justified because the protection against dust is primarily an **occupational safety matter** and a classification would have disproportionate consequences.

The classification as recommended by the RAC is based on a substance-unspecific general particle effect of dust. A specific toxicity of titanium dioxide has not been determined and the property has been assumed for the entire group of PSLT (Poorly Soluble Low Toxicity Particles). An inhalative exposure to titanium dioxide dust that could at least theoretically be within the critical dose range is only to be expected at highly exposed workplaces. However, most EU Member States have already **general limits for dust** in their occupational health and safety legislation. These general limits for dust at the workplace effectively protect humans from the particle effect already. The necessity of a classification of individual substances without a specific toxicity has not been determined. In contrast, a classification of titanium dioxide as potentially carcinogenic would not have any direct legal consequences with regard to occupational health and safety (beyond the obligation to consider a substitution), thereby it

would be **neither suitable for improving occupational health and safety, nor would it be necessary**.

Such a classification would be **disproportionate**, as its consequences, e.g. in the waste legislation, would also affect products in which titanium dioxide is firmly bound in a matrix so that it cannot be inhaled.

- **Question 2:** *What are the views of CARACAL members and observers on the application of **derogations** such as Article 12(b) or Annex I, section 1.3.4?*

The rules in Annex I, 1.3.4 of the CLP regulation are only valid for a very restricted range of products and they merely allow foregoing the *labelling.* The derogation does not have any effect on the *classification* of mixtures and products that include the substance. Therefore, all the disproportionate legal consequences linked to the classification continue to remain in force.

A derogation on the basis of Article 12(b) CLP regulation would require comprehensive and bureaucratic verifications of the "non-bioavailability" for each of the mixtures – which is not feasible in practice. In addition to this, the corresponding criteria for such verification are not yet defined in detail. Therefore, in our view none of these two approaches for a derogation would be a solution.

Fundamentally, the particle effect can only occur if titanium dioxide appears in the "form" (Articles 5(1) and 6(1) of CLP regulation) of alveolar (respirable) powder. Therefore, a specification of the entry in Annex VI of the CLP regulation – and thereby a restriction of the classification entry – to titanium dioxide in a powder form would be in principle legally possible. However, in view of the serious negative consequences we strongly oppose the classification proposal.

- **Question 3***: Is it appropriate to **limit harmonized classification to TiO_2**? or would it not be preferable to **also classify poorly soluble low toxicity particles (PSLT**), or a well-defined group of PSLT, in the same way in a **grouping approach**?*

The discussed general dust effect is valid for the entire group of Poorly Soluble Low Toxicity Particles (PSLT) and would therefore be relevant for all of these substances. The threshold limits for dust at the workplace in most EU Member States already protects from general particle-related inflammatory processes in the lungs as a result of inhalative dust exposure. These rules thereby already implement the suggested group approach when dealing with PSLTs.

Furthermore, it is our opinion that the scientific basis for the classification of the entire PSLT substances group on the basis of a single – controversial – animal experiment study is not given. Also, the classification of an entire group of substances is not appropriate under CLP as the CLP regulation assumes the existence of a substance-specific property.

For further information see annex "Presentation: Harmonized Classification of Titanium Dioxide - November 2017" (171128_Titanium dioxide_EN.pdf)

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Contact details:

Bundesverband der Deutschen Industrie e.V. (BDI)
[redacted]
Umwelt, Technik und Nachhaltigkeit
Breite Straße 29
10178 Berlin, Germany
Phone: +49 [redacted]
E-Mail: [redacted]@bdi.eu

Verband der Chemischen Industrie e.V. (VCI)
Wissenschaft, Technik und Umwelt
Bereich Produktsicherheit
[redacted]
Mainzer Landstraße 55
60329 Frankfurt, Germany
Phone: +49 69 2556-[redacted]
E-Mail: [redacted]@vci.de

Verband der deutschen Lack- und Druckfarbenindustrie e. V. (VdL)
[redacted]
Mainzer Landstraße 55
60329 Frankfurt, Germany
Phone: +49 69 2556[redacted]
E-Mail: [redacted]@vci.de

Verband der Mineralfarbenindustrie e.V. (VdMi)
[redacted]
Mainzer Landstraße 55
60329 Frankfurt am Main
Phone: +49 69 2556-[redacted]
E-Mail: [redacted]@vdmi.vci.de