Inter-Service Consultation  
on the 14th ATP list to the Annex VI of Regulation (EC) No 1272/2008

Dear Commissioner Vella,

The European Commission services have started an Inter-Service Consultation with the aim to update Annex VI (Harmonised classification and labelling for certain hazardous substances) of Regulation (EC) No 1272/2008 for a total of 20 substances. We write to you concerning the substance titanium dioxide (TiO$_2$) which is included in this list. The industries represented by the signatory associations are users of TiO$_2$. We believe that the hazard that has been observed with this substance should not follow the way of an Annex VI entry and we have for that the following reasons:

**TiO$_2$ is safe for consumers and has a societal function**

TiO$_2$ is a chemically inert white powder that is widely used as pigment in products like paints, inks, plastics but also in many other industries such as paper, construction, glass, steel, pharmaceutical, cosmetics, leather, and textiles. It is used in any product that needs whitening. TiO$_2$ provides the highest opacity by far and has no equivalent technical replacement. The substance is an ingredient that is incorporated during manufacturing into these end-products. Consumers buy these end-products and have no access to the powder form of TiO$_2$.

**The proposed classification broadens the scope of the regulation considerably**

It is proposed to classify TiO$_2$ as Carcinogenic Cat. 2 ‘suspected of causing cancer by inhalation’. The observed toxicological effect result is not specific to the substance but to the overload mechanism that can be observed with any inert dust. A classification of TiO$_2$ will put dust effects into the scope of the regulation and thereby sets a precedent for roughly 300 substances with similar dust effects.

**There are existing safeguards for workers against dust**

Relevant dust levels of TiO$_2$ will only occur at the workplace where rules on occupational safety have to be followed. With no hazard for the consumer we consider a classification inappropriate. Warning the European citizen for inhalation of TiO$_2$ dust is ineffective or even misleading, because it is incorporated in the mixtures and lung overload is irrelevant. Exempting mixtures from classification would prevent at least this nuisance.

**Unintended consequences by a classification: no recyclability for millions of products**

Following the proposed classification, products at end of life or left-over that contain 1% or more of titanium dioxide would have to be considered as hazardous waste and could not be used for recycling. Other legislation would ban products that contain TiO$_2$. Under the toy safety directive most colours would be banned from school-paint boxes. To mitigate these impacts the European Commission services consider exemptions.
Alternatives for a way forward have not been fully explored

After expert meetings (CARACAL & REACH Committee) a considerable number of Member States remain with an objection to a classification according Annex VI. They point to non-existing exposure for consumers and extensive negative consequences for mixtures and articles that use TiO₂.

The Member States that object to a harmonised classification are in favour of a discussion on exposure levels for workers and consider occupational dust limits as the more appropriate instrument. Such alternative proposal has been tabled by Germany. It has no effect on downstream legislation and establishes safeguards where needed.

By using an Annex VI entry for TiO₂, the scope of the regulation would be broadened to roughly 300 substances which may be expected to show similar overload dust effects. If such inert dusts were subject to the rules for Occupational Health it would be a lot more effective and proportionate. Even with ‘mixture exemptions’ the downstream legislation has to be adapted with every next such substance.

Our request

We call on you to take note of the reasons mentioned here in evaluating the Annex VI entry of TiO₂ during this Inter-Service Consultation.

We remain at your disposal for any further discussion with you and your services.

Yours sincerely,

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